DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 419, 427, and 488

[CMS–1850–P]

RIN 0938–AV83

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2027 based on our continuing experience with these systems. We also describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment systems. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting Program and the Ambulatory Surgical Center Quality Reporting Program. There are no changes to the Rural Emergency Hospital Quality Reporting Program. We propose to expand the prior authorization requirement to include additional Botulinum Toxin Injection services. We also propose to implement certain provisions of the Consolidated Appropriations Act, 2026, for off-campus outpatient departments of a provider. In addition, this proposed rule announces notices of closure of teaching hospitals and opportunities to apply for available slots. This rule also requests information regarding potential approaches to improve comparability and standardization, particularly for complex contracting methodologies, of the HPT information reported in machine-readable files and consumer-friendly displays. We propose hospital AOs with deeming authority to assess compliance with certain Emergency Medical Treatment and Labor Act (EMTALA) administrative requirements during accreditation and reaccreditation surveys. Finally, we are soliciting comments on a potential separate payment under the Inpatient Prospective Payment System (IPPS) for domestic procurement of personal protective equipment and essential medicines.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 31, 2026.

ADDRESSES: In commenting, please refer to file code CMS–1850–P.

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 submit electronic comments on this regulation to *https://www.regulations.gov/docket/CMS-2026-2344.* Follow the ''Submit a comment'' instructions.

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–1850–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1850–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Regulation coordination questions, contact Gina Aughenbaugh via email at *OutpatientPPS@cms.hhs.gov.*

Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA), contact Melissa Daly via email at *Melissa.Daly@cms.hhs.gov*.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov.*

Ambulatory Surgical Center Covered Procedures List (ASC CPL), contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting Program measures, contact Marsha Hertzberg via email at *Marsha.Hertzberg@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov.*

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Facilities, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov.*

Blood and Blood Products, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov.*

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

CMS Web Posting of the OPPS and ASC Payment Files, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov.*

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C–APCs), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov.*

Device-Intensive Status and No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

Hospital Outpatient Quality Reporting Program measures, contact Kristina Rabarison via email at *Kristina.Rabarison@cms.hhs.gov.*

Hospital Outpatient Quality Reporting Program policies, contact Kimberly Go via email at *Kimberly.Go@cms.hhs.gov.*

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov.*

Hospital Price Transparency, contact Sarah Wheat via email at *PriceTransparencyHospitalCharges@cms.hhs.gov.*

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Medicare OPPS Drug Acquisition Cost Survey, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* or Gil Ngan at *Gil.Ngan@cms.hhs.gov* or Nate Vercauteren at *Nathan.Vercauteren@cms.hhs.gov.*

Method to Control Unnecessary Increases in the Volume of Outpatient Services, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov.*

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Cory Duke via email at

Cory.Duke@cms.hhs.gov or Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

OPPS Brachytherapy, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at *Erick.Chuang@cms.hhs.gov* or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov.*

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov,* Cory Duke via email at *Cory.Duke@cms.hhs.gov,* or Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov.*

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov.*

OPPS Packaged Items/Services, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov.*

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov.*

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov* or Tonya Gierke at *Tonya.Gierke@cms.hhs.gov.*

Outpatient Department Prior Authorization Requirements, contact Yuliya Cook via email at *Yuliya.Cook@cms.hhs.gov.*

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov.*

Potential Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines Issues, please contact *DAC@cms.hhs.gov.*

Provider-Based Attestation Requirements, please contact *CAA_2026_Section_6225@cms.hhs.gov.*

Rural Emergency Hospital Quality Reporting Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov.*

Rural Emergency Hospital Quality Reporting Program measures, contact Melissa Hager via email at *Melissa.Hager@cms.hhs.gov.*

Skin Substitute Products, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

Software as a Medical Service, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov.*

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov.*

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov.*

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* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the 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/.*

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the calendar year (CY) 2012 OPPS/ASC proposed rule, the addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these addenda are published and available only on the CMS website. The addenda relating to the OPPS are available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* The addenda relating to the ASC payment system are available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices.*

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2026 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

I. Summary and Background

A. Executive Summary of this Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2027. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule announces the closure of a teaching hospital and the opportunity to apply for available slots. In addition, this proposed rule updates and refines requirements for the Hospital Outpatient Quality Reporting Program and the Ambulatory Surgical Center Quality Reporting Program. There are no changes to the Rural Emergency Hospital Quality Reporting Program. We propose to expand the prior authorization requirement to include additional Botulinum Toxin Injection services. This proposed rule also

includes proposals to implement certain provisions of the Consolidated Appropriations Act, 2026, for off-campus outpatient departments of a provider. This rule also requests information regarding potential approaches to improve comparability and standardization, particularly for complex contracting methodologies, of the information reported in machine-readable files and consumer-friendly displays. Additionally, we propose hospital AOs with deeming authority to assess compliance with certain EMTALA administrative requirements under 42 CFR 489.20 during accreditation and reaccreditation surveys. Finally, we are soliciting comments on a potential separate payment under the Inpatient Prospective Payment System (IPPS) for domestic procurement of personal protective equipment and essential medicines.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2027, we propose to increase the payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 2.4 percent. This increase factor is based on the proposed inpatient hospital market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), reduced by a proposed productivity adjustment of 0.8 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2027 will be approximately $110.9 billion, an increase of approximately $9.5 billion compared to estimated CY 2026 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services. Under the proposed 340B remedy offset, payments for services at hospitals subject to the 340B remedy offset will be reduced by 3 percentage points.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. In light of the impact of the COVID–19 public health emergency (PHE) on healthcare utilization, we extended our policy to update the ASC payment system using the hospital market basket update an additional 2 years—through CYs 2024 and 2025. For CY 2026, we extended this interim period an additional year—through CY 2026. In this proposed rule, we are extending our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2027). Using the hospital market basket update, for CY 2027, we are increasing payment rates under the ASC payment system by 2.4 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a proposed hospital market basket percentage increase of 3.2 percent reduced by a final productivity adjustment of 0.8 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2027 will be approximately $9.9 billion, an increase of approximately $520 million compared to estimated CY 2026 Medicare payments.

• *Adjustment for Cost-of-Living in Alaska and Hawaii:* For CY 2027, we propose to establish a cost-of-living adjustment (COLA) for outpatient hospital services provided in Alaska and Hawaii that mirrors the COLA provided for inpatient hospital services provided in these States, including any changes finalized in the IPPS for FY 2027.

• *Device Pass-Through Payment Applications:* For CY 2027, we received 19 complete applications for device pass-through payments. We seek public comment on 13 applications (six applicants withdrew). We propose to approve device pass-through payment status for seven applications and deny device pass-through payment status for six applications. We will make final determinations on these applications in this final rule with comment period.

• *Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:* For CY 2027, we propose to continue to expand the ASC covered procedures list (CPL) by adding 618 codes to the ASC CPL that were recommended by stakeholders or are proposed for removal from the IPO list for CY 2027.

• *Changes to the Inpatient Only (IPO) List:* We are continuing to phase out the IPO list by proposing to remove 637 services from the auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory and urinary clinical families from the IPO list for CY 2027.

• *Cross-Program Updates for the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs:* We propose to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs.

• *Hospital Outpatient Quality Reporting Program:* In addition to the cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, we propose updates and refinements to validation and validation reconsideration procedures, including policies applicable to electronic clinical quality measures (eCQMs). We are also issuing a Request for Information on potentially including an Advance Care Planning measure specified for the Hospital Outpatient Department setting.

• *Rural Emergency Hospital Quality Reporting Program:* We are not proposing any updates to the Rural Emergency Hospital Quality Reporting Program in this proposed rule.

• *Ambulatory Surgical Center Quality Reporting Program:* In addition to the cross-program measure proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, we are soliciting information on potential stratification of the All-cause Transfer/Admission measure.

• *Expansion of Category for Hospital Outpatient Department Prior Authorization Process:* We are adding Botulinum Toxin Injection codes to the existing category of services subject to the Hospital Outpatient Department prior authorization process for dates of service on or after July 1, 2027.

• *Partial Hospitalization and Intensive Outpatient Programs:* We propose to update the Partial Hospitalization Program (PHP) and Intensive Outpatient Program (IOP) payment rates for CY 2027 using the methodology we finalized in CY 2026.

• *Payment Adjustment for 340B-Acquired Drugs Based on Results of the Medicare OPPS Drug Acquisition Cost Survey:* Section 1833(t)(14)(D)(ii) of the Act requires the Secretary to periodically conduct surveys of hospital acquisition costs for each specified covered outpatient drug for use in setting the payment rates for such drugs. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, ''Lowering Drug Prices by Once Again Putting Americans First''. Section 5 of the E.O., ''Appropriately Accounting for

Acquisition Costs of Drugs in Medicare'', which directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Accordingly, from January 1, 2026 through April 7, 2026, we conducted a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS. Taking the survey results into account, we propose for CY 2027 to pay ASP minus 33.4 percent for 340B acquired drugs. Statute requires that this policy be implemented in a budget neutral manner, so this proposal would increase OPPS payments for non-drug services by an equivalent amount, which is estimated to be an 8.44 percent increase to non-drug service payments for this proposed rule.

- *Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy.* The Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (88 FR 77150) codified an annual 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services, excluding hospitals that enrolled in Medicare after January 1, 2018, until we estimated that the reduction had fully offset the additional $7.8 billion in non-drug services payments made as part of the prior 340B drug payment policy. This reduction was effective January 1, 2026. For CY 2027, we propose to increase the annual percent reduction to the OPPS conversion factor used to determine the payment amounts for non-drug items and services for hospitals for whom this adjustment applies from 0.5 percent to 3 percent.
- *Request for Information (RFI) on Strengthening the Standardization and Comparability of Hospital Price Transparency Data:* We are requesting information regarding potential approaches to improve comparability and standardization of the HPT information reported in machine-readable files (MRFs) and consumer-friendly displays. We are particularly interested in comments regarding the reporting of contract mechanisms such as outlier payments, stop-loss provisions, rate tiering, and carve-outs. The RFI also seeks public comment on potential approaches to enhance the comparability and usefulness of the consumer-friendly display requirements, including feedback on whether to modify or eliminate the current deemed compliance policy for internet-based price estimator tools, update the required list of shoppable services, and provide additional clarification regarding the items and services included in displayed prices, such as ancillary and bundled services.
- *Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs):* For CY 2027, we propose to use our authority under section 1833(t)(2)(F) of the Act to apply the Physician Fee Schedule equivalent rate for any Healthcare Common Procedure Coding System (HCPCS) codes assigned to the imaging without contrast APCs when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. We propose to exempt rural Sole Community Hospitals from this method to control the unnecessary volume of imaging without contrast services.

3. Summary of Costs and Benefits

In section XXVI. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 88 in section XXVI.C. of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2027 compared to all estimated OPPS payments in CY 2026. We estimate that the proposed policies in this proposed rule will result in a 1.9 percent increase in OPPS payments to providers for services. We estimate that total OPPS payments for CY 2027, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.82 billion compared to CY 2026 payments due to the OPD update, excluding changes in enrollment, utilization, and case-mix. However, for providers subject to the 340B remedy offset, the 340B remedy offset is estimated to reduce payments by $2.3 billion in CY 2027.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Beginning CY 2024, they are also paid for IOP services under the OPPS. Based on our policy to calculate CMHC PHP and IOP costs based on 40 percent of the corresponding proposed hospital-based PHP and IOP costs, we estimate an 8.4 percent increase in CY 2027 payments to CMHCs relative to their CY 2026 payments.

b. Impacts of the Updated Wage Index

We estimate that our update of the wage indexes based on the fiscal year (FY) 2027 IPPS final rule wage indexes will result in no change for urban hospitals under the OPPS and a 0.5 percent increase for rural hospitals. These wage indexes include continued utilization of the Office of Management and Budget (OMB) labor market area delineations based on 2020 Decennial Census data, with updates, as discussed in section II.C. of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

For CY 2027, we propose to continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. For CY 2027, we propose a target PCR of 0.88 to determine the CY 2027 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

There are no significant impacts of our CY 2027 payment policies for hospitals that are eligible for the rural sole community hospital adjustment, as we propose to maintain the policy in the CY 2027 OPPS.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2027 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.4 percent and applying that increase factor to the conversion factor for CY 2026. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 1.9 percent and that rural hospitals will experience an increase in payments of 6.4 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals will experience an increase in payments of 6.4 percent, minor teaching hospitals will experience an increase in payments of 3.9 percent, and major teaching

hospitals will experience a decrease in payments of 2.4 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 2.0 percent in payments, while hospitals with government ownership will experience a decrease of 0.8 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 10.6 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the proposed CY 2027 payment rates, compared to estimated CY 2026 payment rates, ranges between an increase of 35 percent and a decrease of 4 percent.

f. Impact of the Changes to the Hospital Outpatient Quality Reporting Program

Across 3,000 hospitals participating in the Hospital Outpatient Quality Reporting Program, we estimate that our proposed changes, if finalized, would result in a total information collection burden decrease of 16,985 hours at a cost savings of $971,221 beginning with the CY 2029 reporting period/CY 2031 payment determination.

g. Impact of the Changes to the Ambulatory Surgical Center Quality Reporting Program

Across 5,149 ASCs participating in the Ambulatory Surgical Center Quality Reporting Program, we estimate that our proposed changes, if finalized, would result in a total information collection burden decrease of 16,753 hours at a cost savings of $957,937 beginning with the CY 2027 reporting period/CY 2029 payment determination.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use Disorder- Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation Reduction Act, 2022 (Pub. L. 117–169), enacted on August 16, 2022; the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), enacted December 29, 2022; and the Consolidated Appropriations Act, 2026 (CAA, 2026; Pub. L. 119–75), enacted on February 3, 2026.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of

the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments'', for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is generally temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- Indian Health Service (IHS) hospitals; and
- Rural emergency hospitals (REHs).

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital

outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2024, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html.*

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 25, 2025. The recommendations of the Panel for the most recent meeting are available on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment.* Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2022, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (87 FR 68499). We are currently accepting nominations at *https://mearis.cms.gov.*

In addition, the Panel has established an administrative structure that, in part, currently includes the use of two subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The two current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made; and
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 25, 2025, meeting that these subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *https://facadatabase.gov.*

F. Public Comments Received on the CY 2026 OPPS/ASC Final Rule With Comment Period

We received approximately 48 timely pieces of correspondence on the CY 2026 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 25, 2025 (90 FR 53448).

II. Proposed Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000, for each APC group.

For the CY 2027 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2027, and before January 1, 2028 (CY 2027), using the same basic methodology that we described in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53455 through 53457), using CY 2025 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2027, we began with approximately 147 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2025 and before January 1, 2026, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 74 million final action claims to develop the proposed CY 2027 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under ''Downloads'' for the CY 2027 OPPS/ASC proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

Addendum N to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*), includes the proposed list of bypass codes for CY 2027. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2025 and, therefore, includes codes that were in effect in CY 2025 and used for billing. We propose to retain these deleted bypass codes on the proposed CY 2027 bypass list because these codes existed in CY 2025 and were covered HOPD services in that period, and CY 2025 claims data were used to calculate proposed CY 2027 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we propose to add for CY 2027 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2027, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2027 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2025 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2024. For the proposed CY 2027 OPPS payment rates, we used the set of claims processed during CY 2025. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a

hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2025 (the year of claims data we used to calculate the proposed CY 2027 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2025 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices* and included with every proposed and final OPPS rule.

In accordance with our longstanding policy, similar to our finalized policy for CY 2026 OPPS ratesetting, we propose to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including the data in OPPS ratesetting. For CY 2027 and future years, we propose not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2027. The Hospital OPPS page on the CMS website on which this proposed rule is posted (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient)* provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient,* includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2025 claims that are used to calculate the proposed payment rates for the CY 2027 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2027 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN,'' which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2027 OPPS, we propose to continue to remove claim lines with modifier ''PN'' from the ratesetting process.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (90 FR 53457), which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We propose to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR

for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, as it better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) for the proposed CY 2027 payment rates for blood and blood products (which are generally identified with status indicator ''R'').

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- The CY 2005 OPPS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- The CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- The CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 and 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy—cancer treatment through solid source radioactive implants—consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2013 OPPS/ASC final rule with comment period (77 FR 68240 and 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for several reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for most items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2027, except where otherwise indicated, we propose to continue our policy and use the costs derived from CY 2025 claims data to set the proposed CY 2027 payment rates for brachytherapy sources because we propose to use CY 2025 data to set the proposed payment rates for most other items and services that would be paid under the CY 2027 OPPS. With the exception of the proposed payment rates for brachytherapy sources A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie), C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D. of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose for CY 2027 and subsequent years to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). For CY 2027 and subsequent years, we propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, nonstranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2027 and subsequent years, we also propose to continue the policy we implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, for the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2027 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) and identified with status indicator ''U (Brachytherapy Sources, Paid under OPPS; separate APC payment).''

For CY 2018, we assigned status indicator ''U'' to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2 for the brachytherapy source's APC—APC 2648 (Brachytx planar, p-103) (82 FR 59233 through 59234). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2 for APC 2648 (Brachytx planar, p-103) (83 FR 58834 through 58836). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of

$1.02 per mm² may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CY 2020 (84 FR 61157 and 61158). Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, CY 2023, CY 2024, CY 2025, and CY 2026 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760 and 71761, 88 FR 81553, 89 FR 93925, and 90 FR 53458), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CYs 2021 through 2026.

There were no CY 2025 claims available that reported HCPCS code C2645 for the CY 2027 OPPS/ASC proposed rule. Therefore, in the absence of claims data, we propose to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2026 payment rate of $4.69 per mm² for HCPCS code C2645, which we propose be assigned to APC 2648 (Brachytx planar, p-103) for CY 2027. Similarly, there were no CY 2025 claims available for this proposed rule that reported HCPCS A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie), which is assigned to APC 2632, or HCPCS code C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), which is assigned to APC 2636. While both APC 2632 and 2636 have historically been designated as Low Volume APCs, which uses up to 4 years of claims data, we are concerned that 4 years of historical claims data would only yield 2 claims for each APC and that may not be reliable for ratesetting for these APCs for CY 2027. Therefore, we propose to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states in part that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2026 payment rates for APC 2632 and APC 2636 for CY 2027. Specifically, for CY 2027, we propose a payment rate of $396.32 per millicurie for APC 2632 and a payment rate of $89.40 per 1 mm for APC 2636.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C. of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act in the case of APCs 2632, 2636, and 2648 as detailed above.

For CY 2027, we propose to designate five brachytherapy APCs as Low Volume APCs as these APCs met our criteria to be designated as Low Volume APCs.

We continue to invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to *outpatientpps@cms.hhs.gov.*

b. Comprehensive APCs (C–APCs) for CY 2027

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the costliest primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 and 66810). We have gradually added new C–APCs since the policy was implemented beginning in CY 2015, with the number of C–APCs now totaling 74 (80 FR 70332; 81 FR 79584 and 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; 87 FR 71769; 88 FR 81562; 89 FR 93926; and 90 FR 53448).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy, and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot, by statute, be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 and 66801). A list of services excluded from the C—APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website at

https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C–APC service when it appears on an outpatient claim with a primary C–APC service.

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' [1] excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2.'' [2] Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T [3];''
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1.''

The assignment of status indicator ''J2'' to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) [4] for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and self-administered drugs (SADs), unless they function as packaged supplies (78 FR 74868, 74869, and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15 of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.[5]

[1] Status indicator ''J1'' denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2027 Addendum D1 to this proposed rule.

[2] Status indicator ''J2'' denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2027 Addendum D1 to this proposed rule.

[3] Status Indicator ''T'' is defined as a ''Procedure or Service, Multiple Procedure Reduction Applies'' the OPPS payment status is ''Paid under OPPS; separate APC payment.'' Definitions to all OPPS payment status indicators are available in Addenda D1 to this proposed rule.

[4] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3523cp.pdf.*

[5] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line-item charges for services included on the C–APC claim are converted to line-item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). -We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form- or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this proposed rule, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2027, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We list the proposed complexity adjustments for ''J1'' and add-on code combinations for CY 2027, along with all the other proposed complexity adjustments, in Addendum J to this proposed rule

(which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the final geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1,'' payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C–APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies.

Since the implementation of the C–APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C–APC payment when these products appear on a claim with a primary C–APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C–APC service is consistent with our C–APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C–APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C–APC service. In order to ensure payment for new drugs and biologicals described by

HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug or biological described by HCPCS code C9399 from packaging when the drug or biological is included on a claim with a ''J1'' service, which is the status indicator assigned to a C–APC, and a claim with a ''J2'' service, which is the status indicator assigned to comprehensive observation services. See Addendum J for the proposed CY 2027 C–APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI., ''CY 2023 OPPS Payment Status and Comment Indicators'', to add a new definition to status indicator ''A'' to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The current definition of status indicator ''A'', as finalized in the CY 2023 OPPS/ASC final rule with comment period, can be found in Addendum D1. This change ensures the MAC prices claims for drugs or biologicals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug or biological under the OPPS when it appears on the same claim as a primary C–APC service.

(4) Exclusion of Cell and Gene Therapies From the C–APC Policy

As previously discussed in this section, and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), the C–APC policy packages payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861), we finalized defining a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC treats all individually reported codes as representing components of the comprehensive service, we make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), we generally treat all items and services reported on a C–APC claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a comprehensive service. Historically, items packaged for payment provided in conjunction with the primary C–APC service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually SADs, unless they function as supplies (78 FR 74868 through 74869 and 74909).

However, we recognized in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204) that there are rare instances in which cell and gene therapies appear on the same claim as a primary C–APC service and therefore, have their payment packaged with payment for the primary C–APC service. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938), given the unique nature of these therapies, we do not believe they function as integral, ancillary, supportive, dependent, or adjunctive to any of the current primary C–APC services. Additionally, we stated that when these products are administered, they are the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent, or adjunctive to any primary C–APC services.

Therefore, we finalized a policy for CY 2025 and subsequent years (89 FR 93932 through 93938), to not package payment for cell and gene therapies into C–APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C–APC exclusion list. The proposed list of qualifying products can be found in Table 1.

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TABLE 1: CELL AND GENE THERAPIES PROPOSED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2027

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
CARVYKTI	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Skysona	J3387	Injection, elivaldogene autotemcel, per treatment
Lenmeldy	J3391	Injection, atidarsagene autotemcel, per treatment
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
Ryoncil	J3402	Injection, remestemcel-l-rknd, per therapeutic dose
Hemgenix	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose

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We list all proposed C–APC exclusion categories for CY 2027 in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

(5) Exclusion of Non-Opioid Products for Pain Relief Under Section 4135 of the Consolidated Appropriations Act, 2023 From the C–APC Policy

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled ''Access to Non-Opioid Treatments for Pain Relief,'' amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(iv) of the Act). In

particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount. As stated earlier in this section, our current policy is to exclude from the packaged C–APC payment those items and services that are required by statute to be separately paid.

Accordingly, in the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under section 4135 of the CAA, 2023 from the C–APC policy to ensure payment is not packaged into any C–APC and that separate payment is made in accordance with the statute (89 FR 93938 through 93939).

(6) C–APCs for CY 2027

For CY 2027 and subsequent years, we propose to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology- and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any standard APCs to C–APCs in CY 2027; thus, we propose that the number of C–APCs for CY 2027 (see Table 2) would be the same as the number for CY 2026, which is 74 C–APCs (91 FR 8384).

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TABLE 2: PROPOSED CY 2027 C-APCs

C-APC	CY 2027 APC Group Title	Clinical Family
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS
5112	Level 2 Musculoskeletal Procedures	ORTHO
5113	Level 3 Musculoskeletal Procedures	ORTHO
5114	Level 4 Musculoskeletal Procedures	ORTHO
5115	Level 5 Musculoskeletal Procedures	ORTHO
5116	Level 6 Musculoskeletal Procedures	ORTHO
5117	Level 7 Musculoskeletal Procedures	ORTHO
5153	Level 3 Airway Endoscopy	AENDO
5154	Level 4 Airway Endoscopy	AENDO
5155	Level 5 Airway Endoscopy	AENDO
5163	Level 3 ENT Procedures	ENTXX
5164	Level 4 ENT Procedures	ENTXX
5165	Level 5 ENT Procedures	ENTXX
5166	Cochlear Implant Procedure	COCHL
5182	Level 2 Vascular Procedures	VASCX
5183	Level 3 Vascular Procedures	VASCX
5184	Level 4 Vascular Procedures	VASCX
5191	Level 1 Endovascular Procedures	EVASC
5192	Level 2 Endovascular Procedures	EVASC
5193	Level 3 Endovascular Procedures	EVASC
5194	Level 4 Endovascular Procedures	EVASC
5200	Implantation Wireless PA Pressure Monitor	WPMXX
5211	Level 1 Electrophysiologic Procedures	EPHYS
5212	Level 2 Electrophysiologic Procedures	EPHYS
5213	Level 3 Electrophysiologic Procedures	EPHYS
5222	Level 2 Pacemaker and Similar Procedures	AICDP
5223	Level 3 Pacemaker and Similar Procedures	AICDP
5224	Level 4 Pacemaker and Similar Procedures	AICDP
5231	Level 1 ICD and Similar Procedures	AICDP
5232	Level 2 ICD and Similar Procedures	AICDP
5244	Level 4 Blood Product Exchange and Related Services	SCTXX
5302	Level 2 Upper GI Procedures	GIXXX
5303	Level 3 Upper GI Procedures	GIXXX
5313	Level 3 Lower GI Procedures	GIXXX
5331	Complex GI Procedures	GIXXX
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5361	Level 1 Laparoscopy and Related Services	LAPXX
5362	Level 2 Laparoscopy and Related Services	LAPXX
5372	Level 2 Urology and Related Services	UROXX
5373	Level 3 Urology and Related Services	UROXX
5374	Level 4 Urology and Related Services	UROXX
5375	Level 5 Urology and Related Services	UROXX
5376	Level 6 Urology and Related Services	UROXX
5377	Level 7 Urology and Related Services	UROXX
5378	Level 8 Urology and Related Services	UROXX

C-APC	CY 2027 APC Group Title	Clinical Family
5414	Level 4 Gynecologic Procedures	GYNXX
5415	Level 5 Gynecologic Procedures	GYNXX
5416	Level 6 Gynecologic Procedures	GYNXX
5431	Level 1 Nerve Procedures	NERVE
5432	Level 2 Nerve Procedures	NERVE
5433	Level 3 Nerve Procedures	NERVE
5461	Level 1 Neurostimulator and Related Procedures	NSTIM
5462	Level 2 Neurostimulator and Related Procedures	NSTIM
5463	Level 3 Neurostimulator and Related Procedures	NSTIM
5464	Level 4 Neurostimulator and Related Procedures	NSTIM
5465	Level 5 Neurostimulator and Related Procedures	NSTIM
5471	Implantation of Drug Infusion Device	PUMPS
5491	Level 1 Intraocular Procedures	INEYE
5492	Level 2 Intraocular Procedures	INEYE
5493	Level 3 Intraocular Procedures	INEYE
5494	Level 4 Intraocular Procedures	INEYE
5495	Level 5 Intraocular Procedures	INEYE
5496	Level 6 Intraocular Procedures	INEYE
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5627	Level 7 Radiation Therapy	RADTX
5881	Ancillary Outpatient Services When Patient Dies	N/A
8011	Comprehensive Observation Services	N/A

C-APC Clinical Family Descriptor Key:
AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology/
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

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c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high-quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241, 59242, and 59246 through 52950) for further background.

(1) Mental Health Services Composite APC

For CY 2027, we propose to continue our longstanding policy of limiting the aggregate payment for specified less resource intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive- of all outpatient mental health services (88 FR 49572). We refer readers to the April 7, 2000, OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for further background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 and 33581 and 82 FR 59246 and 59247), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate for APC 5863, which was the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital would continue to be paid the payment rate for composite APC 8010. This policy applied in CYs 2018 through 2023.

In the CY 2024 OPPS/ASC proposed rule, we stated that APC 5863 was no longer the maximum partial hospitalization per diem payment rate for a hospital due to the creation of APC 5864, which is four or more hospital-based PHP services per day (88 FR 49572). We solicited comment on whether APC 5864 would be appropriate to use as the daily mental health cap, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital (88 FR 49572). Based on public comments received and our longstanding policy, in the CY 2024 OPPS/ASC final rule with comment period, we finalized APC 5864, four hospital-based PHP services per day, as the daily mental health cap (88 FR 81566).

We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource intensive of all outpatient mental health services. For CY 2027 and subsequent years, we propose to continue this policy that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for four partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010. In addition, we propose to continue to set the payment rate for composite APC 8010 at the same payment rate that we propose for APC 5864, which is a partial hospitalization per diem payment rate for four partial hospitalization services furnished in a day by a hospital.

Under the proposed policy, the Integrated OCE (I/OCE) would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5864 for all the specified mental health services furnished by the hospital on that single date of service by paying for the services through composite APC 5863.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569) we finalized a policy that effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family

performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2027, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2027, except where otherwise indicated, we propose to use the costs derived from CY 2025 claims data to set the proposed CY 2027 payment rates. Therefore, for CY 2027, the proposed payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2025 claims available for the CY 2027 OPPS/ASC proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the internet on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) and are discussed in more detail in section II.A.1.a. of this proposed rule.

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TABLE 3: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2027 APC 8004 (Ultrasound Composite)	**CY 2027 Approximate APC Geometric Mean Cost = $326.30**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2027 APC 8005 (CT and CTA without Contrast Composite) *	**CY 2027 Approximate APC Geometric Mean Cost = $247.29**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2027 APC 8006 (CT and CTA with Contrast Composite)	**CY 2027 Approximate APC Geometric Mean Cost = $484.46**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye

70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
70471	Cta h&n c+ w/noncontrast img
70473	Ct cere prfu aly c+wo ct/cta
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1− regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2027 APC 8007 (MRI and MRA without Contrast Composite) *	**CY 2027 Approximate APC Geometric Mean Cost = $591.20**
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye

70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2027 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2027 Approximate APC Geometric Mean Cost = $954.20**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye

72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr

* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

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3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary

services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payments because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Packaging encourages efficiency and is an essential component of a prospective payment system; therefore, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Proposed CY 2027 Policy on Packaged Items and Services

For CY 2027, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2027, we are not proposing any changes to the current overall packaging policy discussed in II.A.3.a. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

c. Proposed Payment for Diagnostic Radiopharmaceuticals

(1) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in § 419.2(b), we refer to them as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and, prior to CY 2025, all radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

In the CY 2008 OPPS/ASC final rule with comment period, we finalized the packaging status of diagnostic radiopharmaceuticals as part of our overall enhanced packaging approach for the CY 2008 OPPS and subsequent years (72 FR 66635 through 66641). Importantly, we noted that we believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, making it appropriate to package the payment for the diagnostic radiopharmaceutical into the payment for the related nuclear medicine procedure. Higher cost diagnostic radiopharmaceuticals were one specific type of product that, prior to CY 2025, was policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties raised concerns regarding policy packaging of diagnostic radiopharmaceuticals.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222) and CY 2025 OPPS/ASC final rule with comment period (89 FR 93950), we stated that we continue to believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, generally making it appropriate to package payment for them with payment for the related nuclear medicine procedure. However, we stated there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) we finalized a policy to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 for CY 2025. We also finalized a policy of applying similar methodology to that finalized in the CY 2025 OPPS/ASC final rule with comment period for determining the per day costs of drugs and biologicals in order to calculate the per day costs for diagnostic radiopharmaceuticals for CY 2026 and future years (89 FR 93953 through 93955). We noted that any diagnostic radiopharmaceutical with a per day cost at or below that threshold will continue to be policy packaged under our longstanding policy at § 419.2(b)(15) (89 FR 93962 to 93963). Additionally, we finalized the policy that starting in CY 2026 and for subsequent years, we will update the threshold amount of $630 by a forecast of the Producer Price Index (PPI) for Pharmaceuticals for Human Use, Prescription (Bureau of Labor Statistics (BLS) series code WPUSI07003) from IHS Global, Inc (IGI) (89 FR 93955).

In the CY 2025 OPPS/ASC final rule with comment period, we also finalized a policy to pay for nonpass-through, separately payable diagnostic radiopharmaceuticals with per day costs above the designated threshold based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. As we found that the ASP data we had was not usable for the purpose of paying for diagnostic radiopharmaceuticals, we finalized a policy to pay for qualifying nonpass-through diagnostic radiopharmaceuticals with claims data based on mean unit cost data derived

from hospital claims. Additionally, we finalized corresponding modifications to the regulation text at § 419.2(b)(15) and § 419.41 to codify our finalized payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals. In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical refinement to the diagnostic radiopharmaceutical packaging threshold methodology and finalized the CY 2026 diagnostic radiopharmaceutical packaging threshold of $655. For additional information regarding the policy finalized, please reference the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53482 through 53488).

(2) Proposed Diagnostic Radiopharmaceutical Packaging Threshold

For CY 2027, we propose to continue the policy finalized in CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963). Specifically, we propose to continue to calculate the per day cost of diagnostic radiopharmaceuticals based on the methodology described in section V.B.1.b. of this proposed rule, which relies on the methodology finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638).

As finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955), starting in the OPPS/ASC rulemaking for CY 2026 and for subsequent years, we stated we would update the proposed threshold amount of $630 by a forecast of the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) from IHS Global, Inc (IGI) by using most recently available four-quarter moving average PPI levels to trend from the third quarter of the year 2 years prior to the applicable calendar year to the third quarter of the year prior to the applicable calendar year (for example, from the third quarter of 2024 to the third quarter of 2025 for CY 2026). In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 final threshold forward from the third quarter of the CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest $5 increment (90 FR 53482 through 53483). We believed using the most recently available four-quarter moving average PPI levels more appropriately updated the packaging threshold from CY 2025 for payment in CY 2026. For CY 2026 and subsequent updates, we finalized to trend the CY 2025 threshold of $630 forward using the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription for CY 2025 (third quarter) forward using the PPI for Pharmaceuticals for Human Use, Prescription for the applicable payment year (third quarter) (90 FR 53482 through 53488). This is the same as the update factor used for the OPPS drug packaging threshold, where we originally used the four-quarter moving average PPI levels for Pharmaceutical Preparations, Prescription (BLS series code WPUSI07003, formerly BLS series code 32541DRX) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of the applicable payment year (71 FR 68085 and 68086).

Therefore, for CY 2027, we propose to update the CY 2025 $630 threshold amount by the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to trend the $630 threshold forward. Specifically, we propose to use the most recently available forecast of the four-quarter moving average PPI levels for Pharmaceutical for Human Use, Prescription from the third quarter of 2025 to the third -quarter of 2027, and to round the resulting dollar amount to the nearest $5 increment. Based on this methodology, we trended the $630 threshold forward and rounded the resulting dollar amount ($667.44) to the nearest $5 increment, which yields a proposed figure of $665 per day for CY 2027. Consistent with our methodology and practices listed in section V.B.1.b. of this proposed rule, we also propose that if more recent data are subsequently available (for example, a more recent estimate of the PPI for Pharmaceuticals for Human Use, Prescription), we would use such data, if appropriate, to determine the CY 2027 diagnostic radiopharmaceutical packaging threshold in the final rule.

(3) Amount of Separate Payment for Diagnostic Radiopharmaceuticals Exceeding the Threshold

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93959), once we determine that the per day cost of a nonpass-through diagnostic radiopharmaceutical exceeds the cost threshold, proposed to be $665 per day for CY 2027, we will then assign that radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. We propose to continue our current policy for CY 2027, and propose to pay for those nonpass-through, separately payable diagnostic radiopharmaceuticals based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. While, under this authority, we would ordinarily use the ASP methodology under section 1847A of the Act, we continue to find that the ASP data we had was not usable for payment purposes. We continue to believe that arithmetic mean unit cost (MUC) would be an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. Therefore, we propose to continue our current policy and propose for CY 2027 to pay for qualifying diagnostic radiopharmaceuticals with per day costs above the diagnostic radiopharmaceutical packaging threshold based on their arithmetic MUC, which would be derived from calendar year 2025 claims data.

Although we propose to base payment for qualifying radiopharmaceuticals on their arithmetic MUC for CY 2027, we continue to encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While we propose to continue to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2027, we note that manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2027, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPS. We encourage interested parties to submit comments regarding potential issues that may arise that prevent appropriate ASP reporting for diagnostic radiopharmaceuticals. We refer readers to the CY 2025 OPPS/ASC final rule with comment period as it discusses some of the known concerns regarding ASP reporting for diagnostic radiopharmaceuticals (89 FR 93948 through 93963) as well as the CY 2026 OPPS/ASC final rule with comment period (90 FR 53482 through 53488). We reiterate our stance from the CY 2025 OPPS/ASC final rule with comment period, that if we were to use average sales price as the basis of calculating a payment, we believe there must be more consistent, validated, and universal

reporting in order for ASP to be a viable payment methodology (89 FR 93961).

We also reiterate, as we stated in the CY 2025 and CY 2026 OPPS/ASC final rules with comment period (89 FR 93957 and 90 FR 53484), that there could be potential value in the use of ASP data for payment purposes for diagnostic radiopharmaceuticals when reported correctly and by all manufacturers who manufacture a product that is described by a given HCPCS code. We continue to believe that the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals, as well as for therapeutic radiopharmaceuticals. Previously, to facilitate potential future payment for diagnostic radiopharmaceuticals based on ASP, we sought comment from interested parties on how CMS could ensure more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology utilized in future rulemaking. For example, we sought comment on how CMS could update its past guidance, *Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status*,[6] to reflect current clinical practices and to reflect ASP reporting for diagnostic radiopharmaceuticals. Based on our analysis, and input from interested parties, we will be publishing an ASP reporting Framework for Diagnostic Radiopharmaceuticals on the Medicare Hospital Outpatient PPS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

Additionally, as discussed in section V.B.5. of this proposed rule (Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data), we propose to set the payment rate for new diagnostic radiopharmaceuticals that exceed the diagnostic radiopharmaceutical packaging threshold and with HCPCS codes, but which do not have pass-through status and are without claims data, at ASP plus 6 percent. If ASP data for these diagnostic radiopharmaceuticals are not available, we propose to pay WAC plus 3 percent during the product's initial sales period, consistent with our policy described in section V.B.2. of this proposed rule. If the WAC also is unavailable, we propose to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. Following the initial sales period, a payment rate of WAC plus 6 percent would apply, if ASP data for these diagnostic radiopharmaceuticals remained unavailable. We continue to believe the volume of products in this category would typically be very low; however, in these rare situations, we continue to believe it would continue to be appropriate to use ASP plus 6 percent, WAC plus 3 or 6 percent, or 95 percent of AWP until a MUC is available. As we stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93962), it is appropriate to use this payment hierarchy until a MUC is available. There is typically only one manufacturer for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, although reporting of ASP is not a condition of CMS approving a HCPCS application, CMS has the opportunity to actively engage with the manufacturer, or sponsor of a HCPCS application, during the HCPCS application process. This allows for ongoing dialogue and education regarding the unique ASP reporting requirements that may be associated with a particular product, including how to ensure the reported ASP aligns with the dose descriptor for the newly assigned HCPCS code (89 FR 93958). We continue to believe the hierarchy previously specified is appropriate to determine the payment for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, as it is consistent with the typical hierarchy associated with payment for drugs and biologicals paid under the OPPS as discussed in sections V.A. and V.B. of this proposed rule.

(4) Qualifying Diagnostic Radiopharmaceuticals Above the Diagnostic Radiopharmaceutical Packaging Threshold

The HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that exceed the proposed diagnostic radiopharmaceutical packaging threshold are proposed to be assigned to a status indicator of ''K'', indicating separate payment to be paid based on that HCPCS code's arithmetic MUC. A proposed APC and a proposed payment rate are assigned as shown in Addendum B to this proposed rule. HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold are proposed to continue to be assigned to a status indicator of ''N'', indicating packaged payment.

The proposed list of diagnostic radiopharmaceuticals that we calculate as having per day costs that exceeded $665 and their proposed status indicators can be found in Table 4.

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[6] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf.*

TABLE 4: PROPOSED QUALIFYING DIAGNOSTIC RADIOPHARMACEUTICALS WITH PER DAY COSTS EXCEEDING $665

HCPCS Code	Short Descriptor	Proposed CY 2027 Status Indicator Assignment
A4642	In111 satumomab	K
A9507	In111 capromab	K
A9508	I131 iodobenguate, dx	K
A9515	Choline C 11, diagnostic	K
A9521	Tc99m exametazime	E1*
A9532	I125 serum albumin, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9551	Tc99m succimer	K
A9554	I125 iothalamate, dx	K
A9557	Tc99m bicisate	K
A9569	Technetium TC-99m auto WBC	K
A9570	Indium In-111 auto WBC	K
A9572	Indium In-111 pentetreotide	K
A9582	Iodine I-123 iobenguane	K
A9584	Iodine I-123 ioflupane	K
A9586	Florbetapir F18	K
A9587	Gallium Ga-68	K
A9588	Fluciclovine F-18	K
A9591	Fluoroestradiol F 18	K
A9592	Copper cu 64 dotatate diag	K
A9593	Gallium ga-68 psma-11 ucsf	K
A9594	Gallium ga-68 psma-11, ucla	K
A9595	Piflu f-18, dia 1 millicurie	K
A9596	Gallium illuccix 1 millicure	K
A9601	Flortaucipir inj 1 millicuri	K
A9602	Fluorodopa f-18 diag per mci	K
A9608	Flotufolastat f18 diag 1 mci	K
A9800	Gallium locametz 1 millicuri	K
C9067	Gallium ga-68 Dotatoc	K
Q9982	Flutemetamol F18	K
Q9983	Florbetaben F18	K

*Proposed Status Indicator assignment is E1 until compliance with the Medicaid National Drug Rebate Agreement occurs. Once compliance is met, status indicator K would apply.

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Proposed definitions of status indicators can be found in Addendum D1 to this proposed rule. Addenda to this proposed rule can be found on the CMS OPPS web page.

4. Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(iv) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively.

The additional payments required under section 1833(t)(16)(G) of the Act began on January 1, 2025, based on the policy finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94361). In section XIII.E. of this proposed rule, we propose to continue the policy finalized in the CY 2025 OPPS/ASC final rule with comment period for CY 2027. We also propose non-opioid treatments for pain relief that would qualify under this policy for CY 2027 and seek public comment on those product evaluations.

We refer readers to section XIII.E. of this proposed rule-for a summary of this proposal.

5. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53489 through 53490), we applied this policy and calculated the relative payment weights for each APC for CY 2026 that were shown in Addenda A and B of the CY 2026 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53455 through 53480). For CY 2027, as we did for CY 2026, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2027 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT Evaluation or Assessment and Management (E/M) codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2027, as we did for CY 2026, we propose to continue to standardize all the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2027, as we did for CY 2026, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2027 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2026 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2027 unscaled relative payment weights.

For CY 2026, we multiplied the CY 2026 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2025 claims to calculate the total relative payment weight for each service (90 FR 53489). We then added together the total relative payment weight for each of these services to calculate an estimated aggregate weight for the year. For CY 2027, we propose to apply the same process using the estimated CY 2027 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2026 estimated aggregate weight by the unscaled CY 2027 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* Click on the link labeled ''Hospital Outpatient Prospective Payment—Notice of Proposed Rulemaking'' for 2027, which can be found under the heading ''Hospital Outpatient Regulations and Notices'' and open the claims accounting document link, which is labeled ''2027 Proposed Rule OPPS Claims Accounting.''

We propose to compare the estimated unscaled relative payment weights in CY 2027 to the estimated total relative payment weights in CY 2026 using CY 2025 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2027 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2027 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4582 to ensure that the proposed CY 2027 relative payment weights are scaled to be budget neutral. The proposed CY 2027 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the methodology for payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under section 1833(t)(9) of the Act but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this proposed rule) is included in the budget neutrality calculations for the CY 2027 OPPS.

B. Proposed Conversion Factor Update

1. OPD Fee Schedule Increase Factor

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges of the Act (or an amount that is computed and applied with respect to covered OPD services). In the FY 2027 IPPS/Long Term Care Hospital (LTCH) proposed rule (91 FR 19496), consistent with current law, based on IHS Global, Inc.'s (IGI's) fourth quarter 2025 forecast, the proposed FY 2027 IPPS market basket percentage increase was 3.2 percent. We noted that under our regular process for the CY

2027 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2027 IPPS/LTCH PPS final rule. If that forecast is different than the IPPS market basket percentage increase used for this proposed rule, the CY 2027 OPPS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase.

For CY 2027, we propose to use the estimate of the hospital inpatient market basket percentage increase of 3.2 percent as one component to calculate the OPD fee schedule increase factor.

2. Productivity Adjustment

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced 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 defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (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 private nonfarm business productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity ((TFP) previously referred to as multifactor productivity).[7] 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.* In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496), the proposed productivity adjustment for FY 2027 was 0.8 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2027 OPPS/ASC proposed rule would be a reduction of 0.8 percentage point. We also propose that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 hospital inpatient market basket update and the productivity adjustment for the final rule with comment period, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2027 an OPD fee schedule increase factor of 2.4 percent for the CY 2027 OPPS/ASC proposed rule (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.2 percent, less the proposed 0.8 percentage point productivity adjustment).

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2027, we propose to increase the CY 2026 conversion factor of $91.415 by 2.4 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose to further adjust the conversion factor for CY 2027 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to apply an overall budget neutrality factor of 1.0098 for wage index changes by comparing propose total estimated payments from our simulation model using the proposed FY 2027 IPPS wage indexes to those payments using the CY 2026 OPPS wage indexes. We further propose to calculate an additional budget neutrality factor of 0.9951 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis and the CY 2027 proposed transitional exception for low wage index hospitals.

For CY 2027, we propose to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to calculate a CY 2027 budget neutrality adjustment factor for the cancer hospital payment adjustment. We previously finalized transitioning from the target PCR of 0.89 for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reducing the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. We propose a CY 2027 target PCR equal to 0.88 for the cancer hospital payment adjustment, which includes the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act. The proposed CY 2027 estimated payments applying the proposed CY 2027 cancer hospital payment adjustment are greater than the estimated payments applying the CY 2026 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 0.9994 to the conversion factor for the cancer hospital payment adjustment.

We propose to establish a cost-of-living adjustment (COLA) for hospitals in Alaska and Hawaii in the CY 2027 OPPS. We propose a budget neutrality factor of 0.9993 to account for the CY 2027 proposed COLA by comparing proposed total estimated payments from our simulation model without a COLA policy to those with the proposed CY 2027 COLA.

For the CY 2027 OPPS/ASC proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2027 will equal approximately $195.3 million, which represents 0.18 percent of total projected CY 2027 OPPS spending. Therefore, we state that the proposed conversion factor would be adjusted by the difference between the 0.30 percent estimate of pass-through spending for CY 2026 and the 0.18 percent estimate of proposed pass-through spending for CY 2027, resulting in a proposed increase to the conversion factor for CY 2027 of 0.12 percentage point.

We propose that estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2027. We estimate for this proposed rule that outlier payments would be approximately 1.19 percent of total OPPS payments in CY 2026; the 1.00 percent for proposed outlier payments in CY 2027 would constitute a 0.19 percentage point decrease in payment in CY 2027 relative to CY 2026.

In this proposed rule with comment period, we estimate an 8.44 percent increase to nondrug OPPS payment rates as a budget neutral adjustment for the $4.85 billion reduction in OPPS drug payment as a result of the proposed 340B drug payment policy. As part of that proposed policy, we note

[7] *https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.*

that our adjustment in the final rule could potentially change as a result of changes such as updated data, modifications to the estimate methodology, and other factors. For additional discussion of the proposed 340B drug payment policy, please see section V.B.7 of this proposed rule.

For CY 2027, we propose to use a conversion factor of $102.004 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 1.024 (2.4 percent for CY 2027), the required proposed wage index budget neutrality adjustment of approximately 1.0098, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment and the proposed transitional exception of approximately 0.9951, the proposed cost-of-living adjustment of 0.9993, the proposed cancer hospital payment adjustment of 0.9994, the adjustment for drugs purchased under the 340B Program of 1.0844, and the proposed adjustment factor of 1.0012 (an increase of 0.12 percentage point) for the difference in pass-through spending, which results in a proposed conversion factor for CY 2027 of $102.004.

For CY 2027, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above and apply an adjustment factor of 0.9805 to the proposed CY 2027 conversion factor of $102.004. We propose that the hospitals that fail to meet the requirements of the Hospital OQR Program will use a reduced OPD fee schedule update factor of 0.4 percent (that is, the proposed OPD fee schedule increase factor of 2.4 percent further reduced by 2.0 percentage points).

For CY 2027, as previously discussed in section V.B.7, we propose to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies with a 3 percentage point reduction to the OPD fee schedule increase factor. This would result in a proposed reduced conversion factor for CY 2027 of approximately $99.015 for this group of hospitals. The calculations we performed to determine the CY 2027 proposed conversion factor are shown in Table 5.

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TABLE 5: CALCULATION OF CY 2027 PROPOSED OPPS CONVERSION FACTOR

Start: CY 2026 Final OPPS Conversion Factor = **$91.415**
Step 1a: Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2026. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0030), the percentage of outlier spending (0.01) and the percentage of domestic NIOSH/N95 policy (0.0001) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2026. ➢ 1.0000 – (0.0030 + 0.01 + 0.0001) = 0.9869
Step 1b: Divide $91.415 by 0.9869 ➢ $91.415/0.9869 = **$92.628**
Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 1.0098. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with $92.628. ➢ $92.628* 1.0098 = **$93.536**
Step 3: Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9951. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $93.536. ➢ $93.536* 0.9951 = **$93.078**
Step 4: Adjust the conversion factor by cost-of-living adjustment (COLA) of 0.9993. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $93.078. ➢ $93.078*0.9993 = **$93.013**
Step 5: Adjust the conversion factor by the cancer hospital payment adjustment of 0.9994. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $93.013. ➢ $93.013*0.9994 = **$92.957**
Step 6: Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we propose to maintain our current policy, there is no impact on the conversion factor by this policy. ➢ $92.957*1.0000 = **$92.957**
Step 7: Adjust the conversion factor by the proposed 340B drug payment budget neutrality adjustment policy of 1.0844. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with $92.957. $92.957*1.0844 = **$100.802**
Step 8a: Adjust the conversion factor by the OPD fee schedule increase factor of 0.024 for CY 2027. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2027 over CY 2026 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2026. ➢ 1.0000+0.024 = **1.0240**
Step 8b: Multiply $100.802 by 1.0240.

➢ $100.802*1.0240 = **$103.222**
Step 9a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2027. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0018) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2027. ➢ 1.0000 – (0.0018+0.01) = 0.9882
Step 9b: Multiply $103.222 by 0.9882 to get the CY 2027 proposed OPPS conversion factor. $103.222*0.9882 = **$102.004**
Finish: **CY 2027 proposed OPPS Conversion Factor = $102.004**
* *Reduction for Providers Subject to the 340B Remedy Offset* *Step 8:* Multiply $102.004 by 0.9707 to get the CY 2027 proposed OPPS conversion factor for the providers subject to the 340B remedy offset. $101.722*0.9707 = **$99.015**

Please note rounding may affect the numbers in the calculations above.

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C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified in regulation at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related portion or OPPS labor-related share. The scaled weight budget neutrality calculation methodology is discussed in section II.A.5. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for CY 2027. We refer readers to section II.C. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation under ''Downloads'' for this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2027 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount. Under §§ 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000, final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998, OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State, and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2027, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2026 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States''

as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 and 53370; for FY 2014, 78 FR 50590 to 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; FY 2023, 87 FR 49006; FY 2024, 88 FR 58977; for FY 2025, 89 FR 69300; and for FY 2026, 90 FR 36851.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2027 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, an adjustment for occupational mix, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban States, an adjustment to the wage index based on commuting patterns of hospital employees (the out-migration adjustment), the 5 percent cap on any decrease to a hospital's wage index from its wage index in a prior FY, and the transitional payment exception for hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Beginning with FY 2024, we include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and we exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 58971 through 58973). We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) for a detailed discussion of all proposed changes to the FY 2027 IPPS wage indexes.

We note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, 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. That is, a hospital's wage index for FY 2027 would not be less than 95 percent of its final wage index for FY 2026. 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 would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year (subject to any reclassification), and it would not receive a cap for that first year, because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted previously).

Consistent with the FY 2026 IPPS/LTCH PPS final rule (90 FR 36852 through 36854), we discontinued for CY 2026 and subsequent years the low wage index hospital policy under the OPPS (90 FR 53495 through 53496). Under the low wage index hospital policy that we previously adopted for the OPPS (84 FR 61186 through 61188), we increased the wage index for hospitals with a wage index value below the 25th percentile wage index value for a calendar year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2025 IFC (89 FR 80405 through 80421), FY 2026 IPPS/LTCH PPS final rule (90 FR 36852 through 36854) and CY 2026 OPPS/ASC final rule with comment period (90 FR 53495 through 53496) for a detailed discussion regarding the removal of the low wage index hospital policy from the IPPS for FYs 2025 and 2026 and the OPPS for CY 2026.

In the FY 2026 IPPS final rule (90 FR 36855 through 36857), using our authority under section 1886(d)(5)(I)(i) of the Act, we adopted a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. As indicated in that rule, we adopted this temporary payment exception ''to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under prospective payment systems.'' To address these same concerns under the OPPS, we correspondingly adopted a transitional payment exception for CY 2026 under the OPPS using our equitable adjustment authority under section 1833(t)(2)(E) of the Act (90 FR 53496 through 53497). This authority allows the Secretary to establish, in a budget neutral manner, adjustments as determined to be necessary to ensure equitable payments.

The CY 2026 transitional exception policy under the OPPS applied to hospitals that benefited from the CY 2024 low wage index hospital policy. For those hospitals, we compared the hospital's proposed CY 2026 wage index to the hospital's CY 2024 wage index. If the hospital was significantly impacted by the discontinuation of the low wage index hospital policy, meaning the hospital's proposed CY 2026 wage index was decreasing by more than 9.75 percent from the hospital's CY 2024 wage index, then the transitional payment exception for CY 2026 for that hospital was equal to the additional CY 2026 amount the hospital would be paid under the OPPS if its CY 2026 wage index were equal to 90.25 percent of its CY 2024 wage index. This transitional payment exception was applied after the application of the 5-percent cap described at 42 CFR 412.64(h)(7). This policy was budget neutral under the OPPS through the second wage index budget neutrality adjustment applied to the OPPS conversion factor (which currently includes the 5 percent hold harmless cap policy).

In the FY 2027 IPPS/LTCH proposed rule (91 FR 19476 through 19478) we proposed, using our authority under section 1886(d)(5)(I)(i) of the Act, to continue to apply the narrow transitional payment 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 that we adopted in CY 2026. As indicated in that rule, we proposed to continue this temporary payment exception because ''[s]ome 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).'' [8] To address these same concerns under the OPPS, we correspondingly propose to continue the transitional payment exception for CY 2027 under the OPPS that we adopted in CY 2026 using our equitable adjustment authority under section 1833(t)(2)(E) of the Act.

Core Based Statistical Areas (CBSAs) are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes

[8] 91 FR 19477.

for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html.* In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2027, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2027 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2027. Therefore, any policies and adjustments that are finalized for the FY 2027 IPPS post-reclassified wage index would be reflected in the final CY 2027 OPPS wage index beginning on January 1, 2027, if appropriate. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) and the proposed FY 2027 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipps-proposed-rule-home-page.*

Regarding budget neutrality for the CY 2027 OPPS wage index, we refer readers to section II.C. of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2027. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) for a detailed discussion of the proposed changes to the FY 2027 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a ''section 505 out-migration county'' (that is, a county identified under section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2027, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA) (88 FR 49585 through 49586). Furthermore, we propose that the wage index that would apply for CY 2027 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any other policies and adjustments applied to the IPPS wage index. In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5 percent cap on wage index decreases and the previously described proposed transitional payment exception for hospitals significantly impacted by the discontinuation of the low wage index hospital policy.

For CMHCs, for CY 2027, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2027 would continue to include the rural floor adjustment and any other policies and adjustments applied to the IPPS wage index. In addition, the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases and proposed transitional exception. Also, we propose that the wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2027 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipps-proposed-rule-home-page*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2027 IPPS/LTCH PPS proposed rule (available for download via the website noted previously) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2027. We are including the out-migration adjustment information from Table 2 associated with the FY 2027 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule, with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* At this link, readers will find a link to the proposed FY 2027 IPPS wage index tables and Addendum L, associated with this proposed rule.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB control number 0938–0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes new hospitals, defined for this purpose as entities that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate

status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using statewide average CCRs (also referred to as statewide average default CCRs), including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the Claims Accounting Narrative for this proposed rule, which is posted on the CMS website. We propose to calculate the default ratios for CY 2027 using the most recent cost report data.

The statewide average CCRs are available on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices;* click on the link on the left of the page titled ''Annual Policy Files'' and then select the relevant year to download the statewide CCRs and upper limits in the ''Downloads'' section of the web page.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2027

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provides the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. As detailed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53499), we provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2026.

For CY 2027, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2027

1. Background

Since the inception of the OPPS, which was authorized by the BBA, Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress added section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB No. 0938–0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a

complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 and 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 6 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2026.

TABLE 6: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2026

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89
2024	0.88
2025	0.87
2026	0.88

2. Proposed Policy for CY 2027

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage point less than the target PCR that would otherwise apply. Section 16002(b) of the 21st Century Cures Act also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, section 16002(b) of the 21st Century Cures Act provides that the Secretary shall not consider the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. As discussed further below, we are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2027.

To calculate the proposed CY 2027 target PCR, we propose to use the same extract of cost report data from HCRIS used to estimate costs for the CY 2027 OPPS which, in most cases, would be the most recently available hospital cost reports. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2025 claims data that we used to model the impact of the proposed CY 2027 APC relative payment weights (3,374 hospitals) because we believe it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2027 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2023 to 2025; however, the cost reporting periods were predominantly from fiscal years ending in 2024 and 2025. We then removed the cost report data of the 50 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the

calculation of hospital-weighted statistics. We also removed the cost report data of nine hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,315 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.88 for each cancer hospital.

Table 7 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2027, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2027 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2027 payments and costs from the settled CY 2027 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 7: ESTIMATED CY 2027 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2027 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	35.2%
050660	USC Norris Cancer Hospital	19.8%
100079	Sylvester Comprehensive Cancer Center	31.3%
100271	H. Lee Moffitt Cancer Center & Research Institute	16.3%
220162	Dana-Farber Cancer Institute	45.4%
330154	Memorial Sloan-Kettering Cancer Center	42.5%
330354	Roswell Park Cancer Institute	7.8%
360242	James Cancer Hospital & Solove Research Institute	27.1%
390196	Fox Chase Cancer Center	5.3%
450076	M.D. Anderson Cancer Center	52.9%
500138	Seattle Cancer Care Alliance	41.8%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2026, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus $6,225 (the fixed-dollar amount threshold) (90 FR 53502 through 53504). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2025 OPPS payments, using CY 2025 claims available for this proposed rule, is approximately 0.93 percent. Therefore, for CY 2025, we estimate that we did not meet the outlier target by 0.07 percent of total aggregated OPPS payments.

For the CY 2027 OPPS/ASC proposed rule, using CY 2025 claims data and CY 2026 payment rates, we estimate that the aggregate outlier payments for CY 2026 would be approximately 1.19 percent of the total CY 2026 OPPS payments. We provide estimated CY 2027 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

2. Proposed Outlier Calculation for CY 2027

For CY 2027, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for partial hospitalization program (PHP) and intensive outpatient program (IOP) outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We propose to continue our outlier policy that if a CMHC's cost for PHP and IOP services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2027 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus the fixed-dollar threshold.

We calculate the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2026 (90 FR 53502 through 53504). For purposes of estimating outlier payments for CY 2027, we used the hospital-specific overall ancillary CCRs available in the April 2026 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate CY 2027 hospital outlier payments, we inflate the charges on the CY 2025 claims using the same proposed charge inflation factor of 1.15154 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809). We used an inflation factor of 1.07310 to estimate CY 2026 charges from the CY 2025 charges reported on CY 2025 claims before applying CY 2026 CCRs to estimate the percent of outliers paid in CY 2026. The proposed methodology for determining these charge inflation factors is discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we were concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2027 IPPS outlier calculation to the CCRs used to simulate CY 2027 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2027, we propose to apply an adjustment factor of 0.977497 to the CCRs that were in the April 2026 OPSF to trend them forward from CY 2026 to CY 2027. The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809.

To model hospital outlier payments for this CY 2027 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2026 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.977497 to approximate CY 2027 CCRs) to charges on CY 2025 claims that were adjusted (using the proposed charge inflation factor of 1.15154 to approximate CY 2027 charges). We simulated aggregated CY 2027 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2027 OPPS payments. We estimate that a proposed fixed dollar- threshold of $7,100 combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments for CY 2027. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we propose to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer

readers to section XV. of this proposed rule.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight described in section II.A. of this proposed rule. The national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available on the CMS website at ''*Hospital Outpatient Regulations and Notices*'') and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available on the CMS website, see link above) is calculated by multiplying the proposed CY 2027 scaled weight for the APC by the CY 2027 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''Q4,'' ''R,'' ''S,'' ''T,'' ''U,'' or ''V'' (as defined in Addendum D1 to this proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2027 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2027 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. For CY 2027, we propose to apply for the CY 2027 OPPS wage index any adjustments for the FY 2027 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment and a wage index floor of 1.00 in frontier States, in accordance with section 10324 of the Affordable Care Act of 2010. For further discussion of the wage index we are applying for the CY 2027 OPPS, including the low wage index hospital policy, we refer readers to section II.C. of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2027 IPPS wage index, which are listed in Table 3 associated with the FY 2027 IPPS proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* (Click on the link on the left side of the screen titled ''FY 2027 IPPS Proposed Rule Home Page'' and select ''FY 2027 Proposed Rule Tables''.) This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) of the Act or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = 0.40 * (national unadjusted payment rate).

Step 6. If a provider is an sole community hospital (SCH), as set forth in the regulations at § 412.92, or an essential access community hospital (EACH), which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2027 full national unadjusted payment rate for APC 5071 is $811.46. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $795.64. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the proposed full national unadjusted payment is approximately $486.88 (0.60 * $811.46). The labor-related portion of the proposed reduced national adjusted payment is approximately $477.38 (0.60 * $795.64).

Step 2 & 3. The FY 2027 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2027 wage index policies, is 1.3260.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately $645.60 ($486.88 * 1.3260). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately $633.01 ($795.64 * 1.3260).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately $324.58 (0.40 * $811.46). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately $318.26(0.40 * $795.64).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the proposed full national unadjusted payment is approximately $970.18 ($645.60 + $324.58). The sum of the portions of the proposed reduced national adjusted payment is approximately $951.27 ($633.01 + $318.26) as shown in Table 8.

TABLE 8: PROPOSED FULL NATIONAL UNADJUSTED PAYMENT RATE AND PROPOSED REDUCED NATIONAL ADJUSTED PAYMENT RATE

Proposed Full national unadjusted payment rate	Proposed Reduced national adjusted payment rate
$970.18	$951.27

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011,

that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amended section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section ''X.B. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'', of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(C), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2027 through CY 2029 is 90 percent, with beneficiary coinsurance equal to 10 percent.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA were initially implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. On February 9, 2023 and December 14, 2023, we issued initial [9] and revised [10] guidance, respectively, implementing the Medicare Part B Inflation Rebate Program, including the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act.[11] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare.*

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) of the Act requires under the ASC payment system that, in the case of a Part B rebatable drug for which payment is not packaged into a payment for a service, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug described under section 1192(c) of the Act.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and the OPPS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. Consistent with the policy adopted in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance, the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152 (88 FR 79043).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81594), we codified the OPPS program payment and cost as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41, which cross-references the regulations adopted in the CY 2024 PFS final rule (§§ 410.152(m) and 489.30(b)(6)). We also amended the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. Similarly, we codified the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference

[9] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[10] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.*

[11] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

to 42 CFR 489.30(b)(6), which codified the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

In the CY 2025 PFS final rule (89 FR 98228 through 98275), we codified regulations implementing section 11101 of the IRA in newly added 42 CFR part 427, chapter IV, including new provisions at §§ 427.200 and 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined in § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. As finalized, § 427.201(a) establishes that CMS will use the methodology established in such section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage and incorporates references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). Section 427.201(c) provides that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Section 427.201(b) sets forth the calculation of the inflation-adjusted beneficiary coinsurance. We will compare the payment amount in paragraph (b)(3) of such section to the inflation-adjusted payment amount for an applicable calendar quarter; if the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is calculated by multiplying the inflation-adjusted payment amount by 0.20. Section 427.201(b)(3) specifies that CMS will use the published payment amount in quarterly pricing files [12] [13] [14] to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance. If so, such adjusted beneficiary coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. This approach deviates from the rebate calculation approach set forth in § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published payment amount in quarterly pricing files differ.

We note that the cost sharing amounts of rebatable drugs paid under the OPPS published in the quarterly Addendum A and B updates reflect the inflation-adjusted coinsurance applied as a percent of the payment amount that would otherwise apply in accordance with section 1847A(b)(1)(B) or (C) of the Act, as determined by the Secretary pursuant to 1847A(i)(5) of the Act using the methodology in § 427.201. As we explained in the CY 2025 PFS final rule (89 FR 98237), this policy is intended to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount, and we believe this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the ''specified amount'' used to determine rebate amounts. We refer readers to the full discussion at 89 FR 98237 and 98238 for additional details.

2. OPPS Copayment Policy

For CY 2027, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. We refer readers to the November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458). In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles. The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2027, are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2027, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative

[12] See *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[13] See *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.*

[14] See *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda.*

payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20 percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, $162.29 is 20 percent of the full national unadjusted payment rate of $970.18. For APCs with only a minimum unadjusted copayment in Addenda A and B to proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2027, are shown in Addenda A and B to this proposed rule (which are available via the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2027 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

We also note that the co-insurance for a separately payable drug under the OPPS shall not exceed the amount of inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for

these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section X.I. ''Proposed CY 2027 Payment Status and Comment Indicators'' of this proposed rule, we discuss the various status indicators and comment indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, 61 new HCPCS codes were established and made effective on April 1, 2026. Through the April 2026 OPPS quarterly update CR (Transmittal 13686, Change Request 14380, dated March 13, 2026), we recognized several new HCPCS codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 9 (New HCPCS Codes Effective April 1, 2026). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule.

The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment, and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

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TABLE 9: NEW HCPCS CODES EFFECTIVE APRIL 1, 2026

CY 2026 HCPCS Code	CY 2026 Long Descriptor
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
C8007 (retroactive to January 1, 2026)	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring a insertion of a separate distal respiratory sensor electrode or electrode array
C8008 (retroactive to January 1, 2026)	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009 (retroactive to January 1, 2026)	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8010	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
C8011 (retroactive to January 1, 2026)	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012 (retroactive to January 1, 2026)	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013 (retroactive to January 1, 2026)	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C9309	Injection, onasemnogene abeparvovec-brve, per treatment
C9818 (effective January 23, 2026)	suzetrigine, oral, 1 mg
G0680	Detection and quantification of coronary artery calcium and/or aortic valve calcification from algorithmic analysis of computed tomography of the chest with report
G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
J0463	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg
J1164	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	Injection, immune globulin (yimmugo), 100 mg
J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose
J8502	Injection, aprepitant (aponvie), 1 mg
J9003	Leuprolide injectable (camcevi etm), 1 mg
J9183	Gemcitabine intravesical system, 225 mg
J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
J9278	Injection, carboplatin (avyxa), 1 mg
J9601	Injection, linvoseltamab-gcpt, 1 mg
M0233	Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose
M0234	Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose
Q0238	Injection, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg
Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4419	Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4421	Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)

CY 2026 HCPCS Code	CY 2026 Long Descriptor
Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4425	Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)
Q4426	Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4427	Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4429	Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4435	Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Pretect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4439	Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5161	Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg
Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg
0614U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 4 enzyme complexes by stained blue native polyacrylamide gel electrophoresis (PAGE), frozen tissue (muscle, liver, heart, cultured skin fibroblasts), diagnostic qualitative result
0615U	Borrelia burgdorferi (Lyme disease), antibody detection of 26 recombinant protein groups, by immunoassay, IgM
0616U	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk
0617U	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0618U	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
0619U	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk
0620U	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0621U	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
0622U	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0623U	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0624U	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk
0625U	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0626U	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0627U	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk

CY 2026 HCPCS Code	CY 2026 Long Descriptor
0628U	Nephrology (kidney diseaserelated genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles
0629U	Infectious disease (tuberculosis), DNA, analysis of 1 target by PCR with clustered regularly interspaced short palindromic repeat (CRISPR)-based probe detection, plasma or serum, qualitative report as detected or not detected
0630U	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffinembedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2)

2. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2026 update, 98 new codes were established and made effective July 1, 2026. Through the July 2026 OPPS quarterly update CR (Transmittal R13832CP Change Request 14477, dated June 16, 2026) we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective July 1, 2026). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to interim APC assignments and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

TABLE 10: NEW HCPCS CODES EFFECTIVE JULY 1, 2026

CY 2026 HCPCS Code	CY 2026 Long Descriptor
A9574	Injection, ferumoxytol, 1 mg
C1609	Vertebral device, motion-preserving, with screw fixation
C8014	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)
C9310	Injection, leucovorin calcium (avyxa), 1 mg
G0572	Management of new patient with dementia residing in an eligible memory care unit, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible memory care unit, including specialized dementia care units within assisted living facilities or other qualifying memory care settings designed to provide specialized care for individuals with dementia and cognitive impairment)
G0573	Management of established patient with dementia residing in an eligible memory care unit, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible memory care unit, including specialized dementia care units within assisted living facilities or other qualifying memory care settings designed to provide specialized care for individuals with dementia and cognitive impairment)
G0574	Management of new patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)
G0575	Management of established patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)
G0669	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of early cardio-kidney-metabolic (eCKM) conditions (hypertension, or two or more of: dyslipidemia, obesity/overweight with central obesity marker, prediabetes); initial 12-month period; per month.
G0670	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of early cardio-kidney-metabolic (eCKM) conditions (hypertension, or two or more of: dyslipidemia, obesity/overweight with central obesity marker, prediabetes); follow-on 12-month period; per month.
G0671	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of cardio-kidney-metabolic (CKM) conditions (one or more of: diabetes mellitus, chronic kidney disease Stage 3a or 3b, atherosclerotic cardiovascular disease); initial 12-month period; per month.
G0672	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of cardio-kidney-metabolic (CKM) conditions (one or more of: diabetes mellitus, chronic kidney disease Stage 3a or 3b, atherosclerotic cardiovascular disease); follow-on 12-month period; per month.
G0673	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of musculoskeletal (MSK) conditions (chronicmusculoskeletal pain); initial 12-month treatment period; per month.
G0674	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of behavioral health conditions (BH) conditions (one or more of: depression, anxiety); initial 12-month period; per month.
G0675	Outcome-Aligned Payment (OAP) for behavioral health (BH) conditions (one or more of: depression, anxiety); follow-on 12-month period; per month.
G0676	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing cardio-kidney-metabolic conditions (early cardio-kidney-metabolic [eCKM] or cardio-kidney-metabolic [CKM] track); per review.
G0677	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing musculoskeletal (MSK) conditions; per review.
G0678	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing behavioral health (BH) conditions (depression, anxiety); per review.

CY 2026 HCPCS Code	CY 2026 Long Descriptor
G0685	Algorithmic analysis for identification of new lesions and determination of change of existing lesions for advanced metastatic cancer using data sets from 2 or more previously acquired pet or pet/ct studies
J0528	Injection, fosfomycin disodium, 20 mg
J1289	Injection, narsoplimab-wuug, 1 mg
J1577	Injection, immune globulin (qivigy), 100 mg
J2361	Injection, depemokimab-ulaa, 1 mg
J2374	Apraclonidine hydrochloride ophthalmic, 1% solution, 0.1 mL
J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL
J3386	Injection, etuvetidigene autotemcel, per treatment
J3405	Injection, onasemnogene abeparvovec-brve, per treatment
J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj
J9232	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg
M0231	Intravenous infusion, tocilizumabbavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, includes infusion and post administration monitoring, first dose
M0232	Intravenous infusion, tocilizumabbavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, includes infusion and post administration monitoring, second dose
Q0234	Injection, tocilizumab-bavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, 1 mg
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg
Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg
Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg
Q5168	Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
Q5169	Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg
Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg
Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg
1026T	Transvaginal laser photobiomodulation therapy of pelvis, provided by a physician or other qualified health care professional
1027T	Percutaneous insertion or replacement of neurostimulation catheter via left subclavian or left jugular vein into the superior vena cava, with verification of capture of phrenic nerves, mapping and programming, and delivery of transvenous phrenic neurostimulation therapy in ventilated patients, with repositioning when performed, including imaging guidance
1028T	Mapping and programming of neurostimulation catheter with delivery of transvenous phrenic neurostimulation therapy in ventilated patients, with repositioning and verification of left phrenic nerve capture, per session
1029T	Mapping and programming of neurostimulation catheter with delivery of transvenous phrenic neurostimulation therapy in ventilated patients, without catheter repositioning, per session
1030T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; initial 30 minutes

CY 2026 HCPCS Code	CY 2026 Long Descriptor
1031T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1032T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) and digital simulation, cumulative time for up to 30 days; initial 60 minutes
1033T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1034T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; initial 90 minutes
1035T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1036T	Noninvasive hemodynamic assessment with pulmonary pressures and ejection fraction when performed, including passive acquisition of acoustic and electrical signals, augmentative algorithmic analysis, and generation of a clinical report with review, interpretation, and clinical integration by a physician or other qualified health care professional
1037T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant pancreatic tissue, including imaging guidance
1038T	Autologous muscle cell therapy, injection(s) of muscle progenitor cells into the tongue, including esophagoscopy, when performed
1039T	Connectomic analysis of previously performed multi-modal brain magnetic resonance imaging (MRI) requiring physician or other qualified health care professional (QHP) analysis of software- and physician-generated structural and functional maps for integration of cortical grey matter correlation based on resting state functional MRI and mapping of white matter connectivity based on diffusion weighted MRI relative to brain regions, with physician or other QHP interpretation and report
1040T	Bronchoscopy, flexible, with bronchial cryotherapy, 1 lung, including trachea, when performed
1041T	Augmentative algorithmic analysis of encephalographic waveforms to identify the source and propagation of epileptiform activity, including artifact reduction with analysis of 3D localization of spike sources throughout the examination, 3D animations over time of high-amplitude event locations, high-frequency activity locations, and temporal relationships among locations, with interpretation and report by physician or other qualified health care professional, related to a previously performed electroencephalogram (EEG)
1042T	Implantation of absorbable urologic scaffold for prosthetic urethra restoration of reconstructed bladder neck and urethral anastomosis (List separately in addition to code for primary procedure)
1043T	Quantitative magnetic resonance, without imaging, for analysis of liver tissue, including assessment of 1 or more parameters (eg, proton density fat fraction]PDFF], water diffusion, T1-water relaxation time), with automatically generated report.
1044T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; first 5 sq cm or less
1045T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; each additional 5 sq cm, or part thereof (List separately in addition to code for primary procedure)
1046T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; first 50 sq cm or less, or 0.5% of body area of infants and children
1047T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

CY 2026 HCPCS Code	CY 2026 Long Descriptor
1048T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 50 sq cm or less, or 0.5% of body area of infants and children
1049T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
1050T	Insertion, subcutaneous heart failure decompensation monitor, containing sensors that measure, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds
1051T	Removal of subcutaneous heart failure decompensation monitor
1052T	Interrogation device evaluation(s), (in person or remote) up to 30 days, insertable subcutaneous heart failure decompensation monitor, analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report, review and interpretation by a physician or other qualified health care professional
1053T	Programming device evaluation (in person or remote) of subcutaneous heart failure decompensation monitor, with analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report and review and interpretation by a physician or other qualified health care professional
0631U	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected
0633U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), nextgeneration sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm reported as a fetal risk score
0634U	Oncology (breast cancer), cellfree DNA (cfDNA), evaluation of 11 ESR1 variants (E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D) using droplet digital PCR (ddPCR), plasma, reported as positive or negative
0635U	Autoimmune (atopic dermatitis), mRNA, nextgeneration sequencing (NGS), gene expression profiling of 487 genes, noninvasive skin-surface scraping, algorithm reported as likelihood of response to therapy
0636U	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG
0637U	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM
0638U	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG
0639U	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM
0640U	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells
0641U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment
0642U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level
0643U	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for singlenucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability
0644U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification

CY 2026 HCPCS Code	CY 2026 Long Descriptor
0645U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance
0646U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffinembedded (FFPE) tumor tissue DNA, baseline assessment
0647U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patientspecific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)
0648U	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from formalinfixed paraffin-embedded (FFPE) tissue
0649U	Neurology (Alzheimer disease), DNA, targeted nextgeneration sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status
0650U	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLCO1B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function
0651U	Oncology (hereditary cancer), genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing (NGS) and digital multiplex ligation-dependent probe amplification for variants, small indels (<40 base pairs), using saliva, whole blood or nail clipping, interpretive clinical report with variant classification
0652U	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status
0653U	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants
0654U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result
0655U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result
0656U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result
0657U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by nextgeneration sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results
0658U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for singlenucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
0659U	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for singlenucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
90616	Influenza virus vaccine, trivalent (tIRV), mRNA, 37.5 mcg/0.38 mL dosage, for intramuscular use
90639	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 50 mcg/0.5 mL dosage, for intramuscular use

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3. October 2026 HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2026, in the CY 2027 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2027 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2026 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2027, we propose to continue our established policy of assigning comment indicator ''N1'' in Addendum B to this proposed rule for those new HCPCS codes that will be effective October 1, 2026, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2027 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

4. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2027, in the CY 2027 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2028 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2027, we propose to include the new Level II HCPCS codes effective January 1, 2027, in Addendum B to the CY 2027 OPPS/ASC final rule with comment period, which would be incorporated in the January 2027 OPPS quarterly update CR. Specifically, for CY 2027, we propose to continue our established policy of assigning comment indicator ''N1'' in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2027, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2027 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

b. New CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule with comment period, and to finalize the specific APC and status indicator assignments for those codes in the following year's rule.

For the CY 2027 OPPS update, we received the CPT codes that will be effective January 1, 2027, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2027 CPT codes in Addendum O, specifically under the column labeled ''CY 2027 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.'' The final HCPCS code numbers will be included in the CY 2027 OPPS/ASC final rule with comment period. In summary, we solicit public comments on the proposed CY 2027 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2027. The CPT codes listed in Addendum B appear with short descriptors only; therefore, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2027 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

Finally, in Table 11 (Comment and Finalization Timeframes for New and Revised OPPS-Related HCPCS Codes),

we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 11: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2026	HCPCS (CPT and Level II Codes)	April 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II Codes)	July 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II Codes)	October 1, 2026	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period
January 2027	CPT codes	January 1, 2027	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. In addition, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group, the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2027, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to consider changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also

known as the HOP Panel or the Panel) recommendations for specific services for the CY 2027 OPPS update will be discussed in the relevant specific sections throughout the CY 2027 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable regarding the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest median cost (or mean cost if so elected) for an item or service within the same group (referred to as the ''2 times rule'').

The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2027, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2027 OPPS update, we identified the APCs with violations of the 2 times rule, and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we have proposed a 2 times rule exception) in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this proposed rule. Rather, it is published and made available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we have not proposed a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2027 included in this proposed rule are related to changes in costs of services that were observed in the CY 2025 claims data available for CY 2027 ratesetting. Addendum B to this proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2026, OPPS Addendum B Update, which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-update.*

3. Proposed APC Exceptions to the 2 Times Rule

While considering the APC changes that we propose for CY 2027, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2025 claims data available for this proposed rule, we found 27 APCs with violations of the 2 times rule. We applied the criteria as described previously in this section to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2027 and found that all of the 27 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2025 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 12. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 12 lists the 27 APCs for which we propose to make an exception under the 2 times rule for CY 2027 based on the criteria cited above and claims data submitted between January 1, 2025, and December 31, 2025, and Cost-to-Charge Ratios (CCRs), if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

TABLE 12: PROPOSED CY 2027 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5054	Level 4 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5613	Level 3 Therapeutic Radiation Treatment Preparation
5671	Level 1 Pathology
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5722	Level 2 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5735	Level 5 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5742	Level 2 Electronic Analysis of Devices
5791	Pulmonary Treatment
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc* on the CMS website and then follow the instructions to access the MEARIS™ system for OPPS New Technology APC applications.[15]

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2026, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC

[15] Currently approved under OMB control number 0938–0860; expires October 31, 2027.

1491 (New Technology—Level 1A ($0–$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is intended to be budget neutral in comparison to what would have been paid under the previous reasonable-cost payment system, and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and continue to be adequate to ensure access to services. For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have low annual volume, which we consider to be fewer than 100 claims in the year of claims data used for ratesetting (86 FR 63528). Where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access of new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy in the CY 2019 OPPS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. However, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the now-ended New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Despite the universal low volume APC policy, we continued to see payment instability for services with very low claims volume of fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. For CY 2025, we finalized a policy to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period used for the universal low volume policy. Instead of assigning these services to a different New Technology APC based on the very few claims available, we maintained the New Technology APC assignment for each service from the prior year, CY 2024. We refer readers to the CY 2025 OPPS/ASC final rule with comment period for a discussion on the policy (89 FR 94016 through 94018). Consistent with our overall policy regarding use of updated claims data in the final rule with comment period, we finalized our proposal to perform a similar analysis for the final rule with comment period using updated claims data, including determining whether specific HCPCS codes continue to meet the criteria for our universal low volume APC policy or would be subject to our proposed policy to continue exempting services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain the New Technology APC assignment from the previous year.

In the CY 2026 OPPS/ASC final rule with comment period we finalized a continuation of the policy to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from the universal low volume policy moving forward. We finalized to continue this policy in future years, until, or unless, an alternative policy was finalized. We refer readers to the CY 2026 OPPS/ASC final rule with comment period for a discussion on the policy (90 FR 53530 through 53531).

In addition to the universal low volume policy and the policy to exempt services with fewer than 10 claims in the 4-year lookback period, it has been our policy to maintain the New Technology APC assignment for services with zero claims in the claims year used for rulemaking. For CY 2027, since we propose CY 2027 OPPS payment rates based on CY 2025 claims data, if a service has no CY 2025 claims, we propose to maintain the same New Technology APC assignment for CY 2027. We continue to believe this approach is appropriate because, in the absence of new claims data, there is no additional information upon which to base a reassignment. This policy ensures consistency and stability in payment until sufficient claims data become available to support a reassignment to a different New Technology APC or appropriate clinical APC.

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with

the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

For CY 2027, the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 are provided in Addendum A to this proposed rule (which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.*

2. Services in New Technology APCs With Zero Claims for the Rulemaking Period or Under 10 Claims in the 4-Year Lookback Period

For CY 2027, there are several services that have either zero claims for CY 2027 rulemaking (based on CY 2025 claims) or fewer than 10 claims in the previous 4-year lookback period. For CY 2027, we propose to maintain the New Technology APC assignments for services listed in Table 13.

TABLE 13: SERVICES WITH FEWER THAN 10 CLAIMS IN THE LOOKBACK PERIOD OR ZERO CLAIMS FOR CY 2027 RATESETTING

Name of Service	HCPCS Code	# of Single Frequency Claims	Final CY 2026 OPPS FR APC & SI Assignments	Proposed CY 2027 OPPS NPRM APC & SI Assignments
Blinded Procedure for NYHA Class III/IV Heart Failure	C9758	9 claims	1590, T	1590, T
CardiAMP	C9782	3 claims	1590, T	1590, T
Corvia Medical Interatrial Shunt	C9760	2 claims	1592, T	1592, T
DARI Motion Procedure	0693T	0 claims	1505, S	1505, S
Implantable Glucose Monitoring System	0446T	0 claims	1563, T	1563, T
Implantable Glucose Monitoring System	0448T	9 claims	1563, T	1563, T
Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent	C9791	6 claims	1551, T	1551, T
Surfacer Inside-Out Access Catheter	C9780	7 claims	1534, S	1534, S
Transcatheter Atrial Shunt System (TASS)	C9792	1 claim	1537, S	1537, S

3. Procedures Assigned to New Technology APC Groups for CY 2027

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource

utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2027, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1564)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001-$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 ($3001–$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[16] This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA-approved package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana''.

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[17] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself. CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC final rule with comment period, we established a new HCPCS code, C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process (85 FR 85940). For CY 2021, we assigned HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036 (86 FR 63532).

CY 2023 was the first year that claims data were available for HCPCS code C9770; therefore, we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule with comment period, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023 (87 FR 71810).

For CY 2024, we proposed and finalized that we would delete HCPCS code C9770 effective December 31, 2023 and recognize CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) starting January 1, 2024 (88 FR 81617 through 81619). We determined the payment rate for CPT code 0810T using the claims data for HCPCS code C9770 and designated CPT code 0810T as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC. For CY 2024, we finalized assignment of CPT code 0810T to APC 1563 (New Technology—Level 26 ($4001–$4500)) (88 FR 81618). For 2025, claims data for CPT code 0810T was not yet available. Therefore, we continued to use claims data for HCPCS code C9770 to determine the appropriate APC for CPT code 0810T and finalized to continue to assign CPT code 0810T to APC 1563 for CY 2025 (89 FR 94018 and 94019).

CY 2026 was the first year that we had claims data available for CPT code 0810T, and there were 7 claims available. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we used the available combined 43 claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2026, we designated CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 43 combined claims available. Therefore, we used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data from a 4-year lookback period to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC, which was the arithmetic mean cost of $4,327. This fell within the cost band for APC 1563 (New Technology—Level 26 ($4001–$4500)), therefore, we continued to assign CPT code 0810T to APC 1563 for CY 2026 (90 FR 53532).

For CY 2027, there are nine claims available for CPT code 0810T, with a

[16] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[17] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://myspark generation.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf.*

geometric mean cost of $4,183. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we propose to use the available combine claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2027, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 39 combined claims available. This is below the threshold of 100 claims for a service within a year required to designate a service as a low volume service and apply our universal low volume APC policy. Using all available claims for CPT code 0810T and HCPCS code C9770 from the 4-year lookback period, based on 39 claims, we determined the geometric mean cost to be approximately $4,239, the arithmetic mean cost to be $4,587, and the median cost to be $4,502. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean of $4,587 falls within the cost band for APC 1564 (New Technology—Level 27 ($4501–$5000)). Therefore, we propose to reassign CPT code 0810T to APC 1564 for CY 2027. Additionally, we propose to perform a similar analysis using updated claims data, including determining if CPT code 0810T continues to meet the criteria for our universal low volume APC policy, in the CY 2027 OPPS/ASC final rule with comment period and update the APC assignment as needed.

Refer to Table 14 for the final CY 2026 and proposed CY 2027 New Technology APC and status indicator assignment for CPT code 0810T. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 14: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0810T

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS, SI APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	1563, T	1564, T

b. BgRT (APC 1518 and 1523)

Biology Guided Radiation Therapy (BgRT) uses positron-emitting radiopharmaceuticals to control delivery of radiation therapy to treat primary and metastatic lung or bone tumors. During radiation treatment delivery, the same system applies these firing filters to the real-time positron emission tomography (PET) data collected by the radiation treatment delivery machine. Effective January 1, 2024, CMS created HCPCS codes C9794 (Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (*i.e.,* modeling) and C9795 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions) to describe the modeling and treatment delivery portions of the BgRT service. We assigned HCPCS code C9794 to APC 1521 (New Technology—Level 21 ($1901–$2000)) and HCPCS code C9795 to APC 1525 (New Technology—Level 25 ($3501–$4000)) for CY 2024.

For CY 2025, we continued to assign HCPCS code C9794 to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1,950.50 and HCPCS code C9795 to APC 1525 (New Technology—Level 25 ($3501–$4000)) with a payment rate of $3,750.50 because we did not have any claims data for the service.

Effective January 1, 2025, HCPCS codes C9794 and C9795 were replaced by HCPCS codes G0562 and G0563, respectively. For CY 2026, we utilized available claims data for HCPCS codes C9794 and C9795 to propose payment rates for HCPCS codes G0562 and G0563. Due to concerns given the extremely limited number of claims and the substantial decrease that would occur if the proposed rates were finalized, we did not finalize the proposed payment rate changes (90 FR 53533 and 53534). For CY 2026, we finalized the assignment of HCPCS code G0562 to APC 1521 and status indicator ''S'' and HCPCS code G0563 to APC 1524 (New Technology—Level 24 ($3001–$3500)) and status indicator ''S'' (90 FR 53534).

Since HCPCS code G0562 and G0563 were made effective January 1, 2025, and the proposed OPPS payment rates for CY 2027 are based on available CY 2025 claims data, this is the first time that we have available claims for HCPCS codes G0562 and G0563, specifically, for ratesetting. For CY 2027, we propose to designate HCPCS codes G0562 and G0563 as low volume procedures under our universal low volume APC policy, given that there are 24 single frequency claims for G0562 and 47 claims for G0563 during the claims period. For HCPCS code G0562, we determined the arithmetic mean cost to be approximately $1,461, the median cost to be approximately $1,601, and the geometric mean cost to be approximately $1,398. Because the median cost is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The median cost of $1,601 falls within the cost band for APC 1518 (New Technology—Level 18 ($1601–$1700)). Therefore, we propose to assign HCPCS code G0562 to APC 1518 (New Technology—Level 18 ($1601–$1700) with a payment rate of $1,650.50 for CY 2027. For HCPCS code G0563, we determined the arithmetic mean cost to be approximately $2,644; the median cost to be approximately $2,218, and the geometric mean cost to be approximately $2,467. The arithmetic mean cost is the statistical methodology

that estimated the highest cost for the service; therefore, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean cost of $2,644 falls within the cost band for APC 1523 (New Technology—Level 23 ($2501–$3000)). Therefore, we propose to assign HCPCS code G0563 to APC 1523 (New Technology—Level 23 ($2501–$3000) with a payment rate of $2750.50 for CY 2027.

Additionally, we propose to perform a similar analysis using updated claims data, including determining if HCPCS codes G0562 and G0563 continue to meet the criteria for our universal low volume APC policy, in the CY 2027 OPPS/ASC final rule with comment period and update the APC assignments as needed.

Refer to Table 15 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignment for HCPCS codes G0562 and G0563. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 15: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
G0562	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	1521, S	1518, S
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	1524, S	1523, S

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APC 5594).

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. We have explained previously that services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. In the CY 2026 OPPS/ASC final rule we noted that, over the past several years, the claims volumes for CPT codes 78431 and 78433 have increased significantly while the geometric mean costs of the codes have remained relatively stable. We explained that, although we had seen stability in the claims data for CPT codes 78431 and 78433, CPT code 78432, which is closely related to CPT codes 78431 and 78433, continued to have low claims frequency and fluctuating geometric mean costs. We explained that, due to our concerns regarding CPT code 78432 and the lack of an appropriate clinical APC for CPT codes 78431 and 78433 at the time based on resource cost similarity, we finalized to continue to assign CPT codes 78431 through 78433 to New Technology APCs for CY 2026 (90 FR 53536 and 53537). While we believe that cardiac PET/CT services, such as those described by CPT codes 78431 through 78433, are clinically similar to services assigned to the Nuclear Medicine and Related Services APC series, such as CPT codes 78429 and 78430, we previously had concerns that the resource costs for the APC series did not align with the resource costs reflected in the claims data for CPT codes 78431 through 78433. As a result, we previously maintained CPT codes 78431 through 78433 in New Technology APCs.

For CY 2027, we propose changes to APCs 5591–5594 (Nuclear Medicine and Related Services) that includes the shifting of the APC assignments for several codes in that APC series. We refer readers to section III.E. Proposed APC-Specific Policies of this proposed rule for a discussion of the policy proposal. As a result of these proposed changes, the proposed geometric mean costs of the Nuclear Medicine and Related Services APC series have also shifted. We believe that the new geometric mean costs of the proposed Nuclear Medicine and Related Services APC series more closely align with the costs reflected in the claims data for CPT codes 78431 through 78433. Therefore, we propose to assign CPT codes 78431 through 78433 to APC 5594 (Level 4 Nuclear Medicine and Related Services). Refer to Table 16 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignment for CPT codes 78431 through 78433. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 16: FINAL CY 2026 AND PROPOSED CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	1522, S	5594, S
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	1517, S	5594, S
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	1522, S	5594, S

d. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent Into Renal Pelvis (APC 1550)

Effective October 1, 2023, CMS established HCPCS code C9789 (Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed) and assigned it to APC 1559 (New Technology—Level 22 ($2001–$2500)), with a payment rate of $2,250.50 based on our review of the clinical and resource characteristics of this service.

This code may be used to describe the unique procedure associated with the administration of the drug described by HCPCS code J9281 (Mitomycin pyelocalyceal instillation, 1 mg) or similar products. HCPCS code J9281 may be used to describe the product, JELMYTO® (mitomycin for pyelocalyceal solution). The FDA approved JELMYTO® in 2020, and the FDA approved indication and usage for JELMYTO® is as an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG–UTUC).[18]

For CY 2025, the OPPS payment rates were based on available CY 2023 claims data. Because we created HCPCS code C9789 effective October 1, 2023, we had limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only had six claims available for ratesetting, so we maintained the New Technology APC assignment of APC 1559 (New Technology—Level 22 ($2001–$2500)) with a payment of $2,250.50 for CY 2025, based on our CY 2025 policy to maintain the New Technology APC assignment for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy (89 FR 94034).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. HCPCS code C9789 had 222 single frequency claims in CY 2024, which exceeded the 100 claims threshold generally used for the universal low volume APC policy. The geometric mean cost for HCPCS code C9789 was approximately $1,211. Therefore, for CY 2026, we assigned HCPCS code C9789 to APC 1551 (New Technology—Level 14 ($1201–$1300)) with a payment rate of $1,250.50 (90 FR 53542 and 53543).

For CY 2027, the proposed OPPS payment rates are based on available CY 2025 claims data. HCPCS code C9789 has 235 single frequency claims in CY 2025 and the geometric mean cost for HCPCS code is $1,173. Therefore, for CY 2027, we propose to assign HCPCS code C9789 to APC 1550 (New Technology—Level 13 ($1101–$1200)) with a payment rate of $1,150.50.

Refer to Table 17 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignment for HCPCS code C9789. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

[18] Jelmyto Package Insert, Revised January, 2021.

TABLE 17: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	1551, T	1550, T

e. LimFlow TADV Procedure, CPT Code 0620T (APC 1581)

The LimFlow TADV procedure which is described by CPT code 0620T (Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed) is an endovascular procedure that is used to treat patients with chronic limb-threatening ischemia. According to the developer, these patients are no longer eligible for conventional endovascular or open bypass surgery to treat their artery blockage, and without this procedure, they are likely to face limb amputation.

CPT code 0620T was established in January 2021 and was assigned to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of approximately $17,400, which is the highest-paying APC for endovascular procedures. While we proposed to continue to assign CPT code 0620T to APC 5194 for CY 2024, we finalized a reassignment from a clinical APC to a New Technology APC with a higher payment rate based on comments received expressing concern that the low payment rate of the procedure would discourage providers from performing the procedure and deny access to the procedure. For CY 2024, the procedure was assigned to APC 1578 (New Technology—Level 41 ($25,001–$30,000)) (88 FR 81694). For CY 2025 ratesetting, there were 11 single frequency claims for CPT code 0620T in the CY 2023 claims data. As this is below the threshold of 100 claims for a service within a year, we applied our universal low volume APC policy and used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims and the application of the universal low volume APC policy, we assigned HCPCS code 0620T to APC 1579 (New Technology—Level 42 ($30,001–$40,000)) with a payment rate of $35,000.50 based on the median cost of approximately $36,400 (89 FR 94034 through 94036).

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. There were 19 single frequency claims for 0620T in the CY 2024 claims data. As this is below the threshold of 100 claims for a service within a year, we proposed to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims and the application of the universal low volume APC policy, for CY 2026. we assigned HCPCS code 0620T to APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment rate of $45,000.50 based on the arithmetic mean cost of approximately $43,748 (90 FR 53543 and 53544).

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. There were 28 single frequency claims for 0620T in the CY 2025 claims data. As this is below the threshold of 100 claims for a service within a year, we propose to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, we have determined that the arithmetic mean is approximately $51,748; the median is approximately $46,455; and the geometric mean cost is approximately $47,513. Of these, the arithmetic mean is the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for APC 1581 (New Technology—Level 44 ($50,001–$60,000)). Therefore, for CY 2027, we propose to designate this service as a low volume service under our universal low volume APC policy and to assign HCPCS code 0620T to APC 1581 (New Technology—Level 44 ($50,001–$60,000)) with a payment rate of $55,000.50.

f. Liver Histotripsy Service (APC 1575)

CPT code 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.[19] When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed (absent the cost of the device) each time it is reported on a claim. On March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, payment for CPT code 0686T in CY 2024

[19] *ClinicalTrials.gov.* ''The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/study/NCT04573881.*

reflected payment for both the service that was performed and the device used each time it was reported on a claim. For CY 2024, we assigned CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50 (88 FR 81631 through 81633). For CY 2025, we continued to assign CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000) due to our CY 2025 policy to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, and based on the fact that there were only three claims for CPT code 0686T in the prior 4-year period (89 FR 94036 and 94037).

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. For the CY 2026 OPPS/ASC proposed rule, we identified 94 claims for CPT code 0686T within this period. As this was below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume APC policy and used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 0686T to the appropriate New Technology APC. We identified $32,307.41 as the arithmetic mean, $20,577.77 as the median, and $21,264.91 as the geometric mean. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT code 0686T. However, six additional claims were processed since the CY 2026 OPPS/ASC proposed rule, bringing the total number of claims to 100. Since the total number of CY 2024 single-frequency claims for CPT code 0686T surpassed the 99-claim threshold for the universal low-volume APC policy, we used the geometric mean cost ($16,008) of the CY 2024 claims data for CPT code 0686T to set the payment rate for CY 2026 under our standard ratesetting methodology, rather than the highest of the three statistical methodologies over a 4-year lookback period. Due to the updated claims data available for the CY 2026 OPPS/ASC final rule with comment period, we finalized a New Technology APC assignment for CPT code 0686T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of around $17,500.50, which was the same APC to which the service was assigned in CY 2025 (90 FR 53544 and 53545) .

For CY 2027, the OPPS payment rates are proposed to be based on available CY 2025 claims data. We have identified 166 single claims for CPT code 0686T within this period. As this surpasses the 99-claim threshold for the universal low volume APC policy for a service within a year, we propose to assign CPT code 0686T using our standard ratesetting methodology using the geometric mean cost to set the payment rate for CPT code 0686T. The geometric mean cost of CPT code 0686T is approximately $14,311. The geometric mean falls within APC 1575 (New Technology—Level 38 ($10,001–$15,000)). Therefore, for CY 2027, we propose to assign CPT code 0686T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50.

Refer to Table 18 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignments for CPT code 0686T. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 18: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	1576, S	1575, S

g. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1518)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant,[20] for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). This is the first FDA approval of esketamine for any use.

Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation and respiratory depression caused by esketamine nasal spray administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The Spravato™ REMS program requires, among other requirements, that the esketamine nasal spray be dispensed and administered to enrolled patients in health care settings that are certified in

[20] Subsequently, the FDA approved a prior approval supplemental new drug application (sNDA) providing for the following labeling modification: expansion of the indication to include monotherapy of Spravato™ (esketamine) for treatment resistant depression (TRD). See *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/211243Orig1s016ltr.pdf*.

the REMS. See *www.fda.gov* for more information regarding the Spravato™ REMS program requirements.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of at least 2 hours post-administration observation of the patient under direct supervision of a health care professional in the certified health care setting. Refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105); see also the Spravato REMS document and Spravato labeling available on the FDA website.[21]

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient who requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine.

For CY 2025, HCPCS code G2082 was assigned to APC 1513 (New Technology—Level 13 ($1101–$1200)) with a payment rate of $1,150.50 and HCPCS code G2083 was assigned to APC 1516 (New Technology—Level 16 ($1401–$1,500)) with a payment rate of $1,450.50.

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2027, we propose to assign HCPCS codes G2082 and G2083 to New Technology APCs based on each of the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to APC 1513 (New Technology—Level 13 ($1101–$1200)) with a payment rate of $1,150.50 based on its approximate geometric mean cost of $1,181, which was calculated using the available 742 single frequency claims from CY 2025 claims data. We also propose to maintain the APC assignment for HCPCS code G2083 (APC 1518 (New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50 based on its approximate geometric mean cost of $1,648, which was calculated using the available 5,741 single frequency claims from CY 2025 claims data. As we continue to gather adequate claims data on these codes, we invite public comment on the appropriate clinical APC assignments for HCPCS codes G2082 and G2083.

Please refer to Table 19 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignments for HCPCS code G2082 and G2083. The proposed CY 2027 payment rates for these CPT codes can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 19: FINAL CY 2026 AND PROPOSED CY 2027 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	1512, S	1513, S
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	1517, S	1518, S

[21] The REMS document is available at *https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems,* and labeling can be found at *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

h. SAINT Neuromodulation System (APCs 1511, 1520, 1521 and 1523)

The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex to treat major depressive disorder (MDD). The patient first receives structural MRI and functional MRI scans that are analyzed by the provider to identify and localize the personalized stimulation target in the patient's dorsolateral prefrontal cortex. Once the areas targeted for treatment are identified, the patient receives non-invasive magnetic stimulation in the targeted area. The patient has 10 treatment sessions per day with each treatment session lasting 10 minutes followed by 50 minutes of rest before another treatment session occurs. The treatment is administered over 5 days for a total of 50 sessions of non-invasive magnetic stimulation therapy. There are four CPT codes listed below that describe the MRI scans that are used to target the treatment and describe the administration of the non-invasive magnetic stimulation therapy.

- 0889T—Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation.
- 0890T—Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day.
- 0891T—Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day.
- 0892T—Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day.

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. However, CPT codes 0889T, 0890T, 0891T, and 0892T did not become effective until July 1, 2024, which means there were no claims data for the procedures described these CPT codes. We assigned our proposed rates for these services based on our evaluation of the resources needed to perform these services.

Because we only had a partial year of data for CY 2026 rulemaking, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the current APCs assignments for CPT codes 0889T, 0890T, 0891T, and 0892T.

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. We note that this is the first year that we have a full year of claims data. We identified 74 single frequency CY 2025 claims for ratesetting for CPT code 0889T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0889T is $673, the median cost is $971, and the arithmetic mean cost is $776. The median is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0889T to APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50.

We identified 73 single frequency CY 2025 claims for ratesetting for CPT code 0890T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0890T is $1,750, the median cost is $1,868, and the arithmetic mean cost is $1,955. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0890T to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1950.50.

We identified 19 single frequency CY 2025 claims for ratesetting for CPT code 0892T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0892T is approximately $2,649, the median cost is approximately $2,193 and the arithmetic mean cost is approximately $2,719. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0892T to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

For CPT code 0891T, the OPPS payment rate is proposed based on available CY 2025 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2027, we propose to assign CPT code 0891T to a New Technology APC based on the code's geometric mean costs. Specifically, we propose to assign CPT code 0891T to APC 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50 based on its approximate geometric mean cost of $1,885, which is calculated using the available 241 single frequency claims from CY 2025 claims data. Please refer to Table 20 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignments for CPT codes 0889T, 0890T, 0891T, and 0892T.

The proposed CY 2027 payment rates for these CPT codes can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 20: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0889T, 0890T, 0891T, AND 0892T

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation	1511, S	1511, S
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	1525, S	1521, S
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	1525, S	1520, S
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	1525, S	1523, S

i. Skin Cell Suspension Autograft (SCSA) Procedures (CPT Codes 15X19 Through 15X22) (APC 1575)

Effective January 1, 2025, both CPT code 15013 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin) and HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)) describe the preparation step of a skin cell suspension autograft (SCSA) procedure to treat acute thermal burn injuries. Both codes describe the preparation step of a three-step SCSA procedure: harvesting, preparation, and application. The difference between the codes is that CPT code 15013 describes the manual preparation of the SCSA, and HCPCS code C8002 describes the automated preparation of the SCSA. Due to the similarities between the procedures, in the CY 2025 OPPS/ASC final rule with comment period, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1567 (New Technology—Level 30 ($6,001–$6,500)) with a payment rate of $6,250.50 and status indicator ''T''. In the CY 2025 OPPS/ASC final rule with comment period, we noted that we believed the sum of the payment rates for the three-step process should approximate $10,000. However, because of the effect of the multiple procedure reduction, the total payment for the skin cell suspension autograft furnished using the RECELL System would have been approximately $8,000, contrary to the intended target of $10,000 as stated in the CY 2025 OPPS/ASC final rule with comment period. To correct this error, in the CY 2025 OPPS/ASC Correction Notice, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 ($7,001–$7,500)) with a payment rate of $7,250.50 and status indicator ''S'' (Procedure or service, not discounted when multiple, paid under OPPS; separate APC payment).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. Since CPT code 15013 and HCPCS code C8002 were not effective until January 1, 2025, we did not have any claims for either code for CY 2024. Therefore, for CY 2026, we finalized to continue to assign CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 ($7,001–$7,500)) with a payment rate of $7,250.50.

Effective January 1, 2027, CPT codes 15011 through 15018 will be deleted and replaced with a bundled four code structure: CPT code 15X19 through 15X22:

- CPT 15X19: Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1 percent of body area of infants and children
- CPT 15X20: each additional 100 sq cm, or each additional 1 percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
- CPT 15X21: Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children

• CPT 15X22: Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1 percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Unlike CPT codes 15011 through 15018, which provide a three step-based coding structure with each procedural step billed separately, CPT codes 15X19 through 15X22 provide a simplified bundled coding structure based on anatomic size.

In light of these coding changes, we propose for CY 2027 to maintain overall payment rates for the SCSA procedure, as we do not believe that changes in coding structure alone warrant changes in payment for a procedure that remains clinically unchanged. The proposed APC and status indicator assignments for CPT Codes 15X19 through 15X22 are provided in Table 21. Due to the new bundled coding structure, for CY 2027 we also propose to delete HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)), which describes the automated preparation step of the SCSA procedure.

TABLE 21: PROPOSED CY 2027 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NEW CPT CODES 15X19 THROUGH 15X22 EFFECTIVE JANUARY 1, 2027

CPT Code	Long Descriptor	Proposed CY 2027 OPPS APC, SI
15X19	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	1575, S
15X20	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A, N
15X21	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	1575, S
15X22	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A, N

The proposed CY 2027 payment rates for CPT codes 15X19 through 15X22 can be found in Addendum B to this proposed rule via the internet on the CMS website.

j. Renal Histotripsy Service (APC 1534)

HCPCS code C9790 (Histotripsy (that is, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) was created October 1, 2023, and was used to describe the Medicare approved Category B IDE (investigational device exemption) clinical study involving the renal histotripsy procedure associated with the use of the HistoSonics Edison System. CPT code 0888T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) replaced HCPCS code C9790 effective July 1, 2024.

Renal histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy solid renal tumors and is currently in a prospective, multi-center, single-arm pivotal trial designed to evaluate the effectiveness and safety of the device for the destruction of kidney tissue by treating primary solid renal tumors. Because the renal histotripsy clinical study is designated as a Category B (non-experimental/investigational) IDE study, the Medicare payment for CPT code 0888T reflects payment for both the service that is performed, and the device used each time it is reported on a claim. For CY 2025 we assigned CPT code 0888T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50 based on the previous APC and status indicator assignments for HCPCS code C9790.

For CY 2026, the proposed OPPS payment rates were based on available CY 2024 claims data. We had identified one single frequency claim for HCPCS code C9790 and eight single frequency claims for CPT code 0888T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we finalized maintaining the APC assignment for CPT code 0888T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50.

For CY 2027, the proposed rates are based on available CY 2025 claims data. We identified 14 single frequency CY 2025 claims for ratesetting for CPT code 0888T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0888T is approximately $5,940, the median cost is approximately $6,740 and the arithmetic mean cost is approximately $8,145. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0888T to APC 1534 (New Technology—Level 34 ($8001–$8500)) with a payment rate of $8,250.50.

Refer to Table 22 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignment for CPT code 0888T. The proposed CY 2027 payment rates for this CPT code can be found in

Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 22: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE RENAL HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC
0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	1576, S	1534, S

4. CY 2027 Proposals for SaMS Procedures Currently Assigned to New Technology APCs

For CY 2027, we propose an interim payment policy for software-based medical services with algorithmic analyses, which is detailed in section X.B. of this proposed rule. Since this CY 2027 proposal involves services assigned to New Technology APCs, this section specifically addresses the interaction between software-based services with algorithmic analyses that are currently assigned to new technology APCs for CY 2026, including the CY 2027 proposed changes to terminology and status indicator assignments. For the full discussion on proposed CY 2027 policies on software-based medical services with algorithmic analyses, including services that are currently assigned to clinical APCs for CY 2026 and analyses currently paid under the Clinical Lab Fee Schedule (CLFS), we refer readers to section X.B. of this proposed rule with comment period.

For CY 2027, we propose three changes regarding software-based medical services with algorithmic analyses. First, we propose to change the terminology from SaaS (Software as a Service), which is how we have referred to these services in prior rulemaking, to Software as a Medical Service (SaMS). For a detailed discussion on the rationale for this proposed terminology change from SaaS to SaMS, we refer readers to section X.B. of this proposed rule with comment period.

Second, for SaMS that are currently assigned to new technology APCs for CY 2026, we propose to maintain the current new technology APC assignments under our equitable adjustment authority at section 1833(t)(2)(E) of the Act for CY 2027. While we typically apply our standard rate-setting methodologies for all services assigned to new technology APCs, such as the universal low-volume policy or making adjustments based on geometric mean cost using available claims data, we are not proposing to do so for SaMS because this is an interim policy. As discussed in section X.B. of this proposed rule, we propose to use CY 2027 as a transitional period to take an incremental step toward developing a more comprehensive and appropriate payment methodology for services we propose to identify as SaMS. In light of this broader policy objective, we believe it is important to minimize potential disruptions in payment for SaMS during this period. Additionally, given the evolving nature of these types of services and anticipated potential policy changes in the future, we believe maintaining current payment levels for CY 2027 is a reasonable step while we continue to refine a more comprehensive payment framework for these services. We note that this approach of maintaining payment is not unusual for SaMS services, as we have historically used our equitable adjustment authority to maintain the new technology APC assignments for some SaMS when there have been concerns regarding low volume and limited claims data. Consistent with this approach, we propose to maintain the existing new technology APC assignments for SaMS rather than assign payment rates based on current claims data. Third, we propose to assign SaMS assigned to new technology APCs to a proposed new status indicator ''O1''—Software as a Medical Service, paid under OPPS; separate APC payment. We refer readers to section XI. of this proposed rule with comment period for the payment status of status indicator ''O1.''

We refer readers to section X.B. of this proposed rule for a full discussion on our CY 2027 proposals for SaMS.

(1) Atherosclerosis Imaging-Quantitative Computer Tomography (AI–QCT) (APC 1511)

Atherosclerosis Imaging-Quantitative Computer Tomography (AI–QCT) is a software-based service with algorithmic analysis that assesses the extent of coronary artery disease severity. This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

- 0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report.
- 0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.
- 0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.
- 0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

Of these four CPT codes, only CPT code 0625T was determined to be separately payable in the OPPS and was assigned to status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) starting October 1, 2022. We assigned CPT code 0625T to a separately payable status indicator based on the technology and its potential utilization in hospital outpatient departments, our evaluation of the service, as well as input from our medical advisors. The procedure was assigned to APC 1511 (New Technology—Level 11 ($900–$1000)) with a payment rate of $950.50 for CY 2023.

For CY 2024, the OPPS payment rates were based on available CY 2022 claims data. There were 37 claims for CPT code 0625T during this time period. As this was below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0625T as a low volume service under our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately $3.70, the arithmetic mean cost to be approximately $4.10, and the median cost to be approximately $3.50. Under our universal low volume new technology APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology Level 1A—(0–$10)) with a payment rate of $5.00. However, we acknowledged that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the CY 2022 claims available only reflected 2 months of data, we were concerned that we did not have sufficient claims data to justify reassignment to another new technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within new technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 69902), for CY 2024, we finalized our proposal to maintain CPT code 0625T's assignment to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50 rather than applying the universal low volume APC policy (88 FR 81649).

For CY 2025, there were only three available claims for 0625T. We continued to have concerns that we did not have sufficient claims data to justify reassignment to another New Technology APC based on the CY 2023 geometric mean cost of $180. Therefore, we used our authority under section 1833(t)(2)(E) for CY 2025 to continue to assign CPT code 0625T to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50 (89 FR 94039).

Effective January 1, 2026, the AMA CPT Editorial Panel created a new Category I CPT code for AI–QCT: CPT code 75577 (Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified healthcare professional). CPT codes 0623T–0626T were deleted and replaced with CPT code 75577. Since CPT code 75577 was effective on January 1, 2026, we will not have claims data available for ratesetting for this code until the CY 2028 rulemaking cycle. However, as CPT code 0625T was still in use until December 31, 2025, we determined the payment rate for CY 2026 for CPT code 75577 using the available CY 2024 claims data for CPT code 0625T.

For the CY 2026 OPPS/ASC proposed rule, there were 22 separately payable claims in the CY 2024 data reported for CPT code 0625T with a geometric mean cost of approximately $496 (90 FR 53539). We continued to have concerns that we did not have sufficient claims data to justify reassignment to another APC based on the 4-year lookback period, which determined the highest value to be the arithmetic mean of $243. Therefore, we used our authority under section 1833(t)(2)(E) of the Act for CY 2026 to assign CPT code 75577 to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50 (90 FR 53540).

For CY 2027, we propose to designate the AI–QCT procedure as a SaMS procedure, as such term is provided in section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT code 75577 using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignment, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignment for CPT code 75577 to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50. Additionally, we propose to assign CPT code 75577 to proposed new status indicator ''O1'' to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(2) LiverMultiScan Service (APC 1511)

CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session; single organ) and 0649T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) became effective July 1, 2021 and are associated with the LiverMultiScan service.

LiverMultiScan is a software-based service with algorithmic analysis that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. In accordance with our add-on codes policy for SaaS [22] (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes.

[22] We note that at the time that the add-on code policy was created (87 FR 72032 through 72033), we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

Thus, CPT code 0649T, the add-on code for LiverMultiScan, is assigned to the identical APC and status indicator as CPT code 0648T, the standalone code for the same service.

For CY 2024, CY 2025, and CY 2026, we used our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0648T and 0649T to APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50 (90 FR 53545 and 53546).

For CY 2027, we propose to designate the LiverMultiScan service as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT codes 0648T and 0649T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignment for CPT codes 0648T and 0649T to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(3) Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP is a software-based service with algorithmic analysisthat applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine what the next management step should be for the patient (for example, CT surveillance versus invasive procedure). In accordance with our SaaS add-on codes policy [23] (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0722T, the add-on code for the Optellum LCP service, is assigned to the identical APC and status indicator as CPT code 0721T, the standalone code for the same service.

For CY 2024, we assigned CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 ($601–$700)) (88 FR 81640 and 81641).

For CY 2025, we continued to assign CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50 based on our CY 2025 policy to maintain new technology APC assignments for CY 2025 for new technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy (89 FR 94039 through 94041).

For CY 2026, we finalized OPPS payment rates for CPT codes 0721T and 0722T based on CY 2024 claims data, which would have resulted in assignment to APC 1502 (New Technology—Level 2 ($51–$100)). However, due to limited claims data, the resulting approximate 90 percent reduction in payment, and questions we had regarding potential adjustments to our payment methodologies to reflect the underlying value of SaMS, we instead used our authority under section 1833(t)(2)(E) of the Act to maintain the APC assignment. Therefore, for CY 2026, we continued to assign CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50 (90 FR 53546 and 53547).

For CY 2027, we propose to designate the Optellum LCP service as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT codes 0721T and 0722T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignments for CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 ($601–$700) with a payment rate of $650.50. Additionally, we propose to assign CPT codes 0721T and 0722T to proposed new status indicator ''O1'' to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(4) Quantitative Magnetic Resonance (QMR) for Analysis of Tissue Composition (APC 1511)

Effective January 1, 2022, CPT codes 0697T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session; multiple organs) and 0698T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)) are associated with the CoverScan, which is a software-based service with algorithmic analyses. This service is a medical image management and processing software package that analyzes MR data and provides quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas, and kidney. For CY 2024, we assigned CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 ($900–$1,000)).

For CY 2025, there were fewer than 100 claims for ratesetting and because we recognized that the number of claims used to apply our universal low volume policy (using the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data) may not have represented the cost of this SaaS, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to

[23] We note that when the add-on code policy was created in the CY 2023 OPPS/ASC final rule with comment period, we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

continue to assign CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 ($900–$1,000)) with a payment of $950.50. In accordance with our SaaS add-on codes policy [24] (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0698T, the add-on code for CoverScan was assigned to the identical APC and status indicator as CPT code 0697T, the standalone code for the same service (89 FR 94041 to 94043).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. We identified 55 single frequency claims for CPT code 0698T and no claims for CPT code 0697T in CY 2024. Because the standalone service and add-on services are identical, we believed it was important for purposes of ratesetting to use the data that is available, whether it was associated with the standalone code or the add-on code, to determine appropriate payment. As the 55 single frequency claims were below the threshold of 100 claims for a service within a year, we would have proposed applying our universal low volume APC policy and would have used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0697T and 0698T to the appropriate New Technology APC. Our analysis of the combined data, zero claims for CPT code 0697T and 137 claims for CPT code 0698T, yielded a geometric mean cost of approximately $422, an arithmetic mean cost of approximately $600, and a median cost of approximately $777. The median cost was the statistical methodology that estimated the highest cost for CPT codes 0697T and 0698T. Based on the median cost, we would have proposed to assign CPT codes 0697T and 0698T to APC 1509 (New Technology—Level 9 ($701–$800)) with a payment of $750.50.

For CY 2026 OPPS/ASC final rule with comment period (90 FR 53547 to 53549), we recognized that the few claims available for CPT codes 0697T and 0698T may not have truly represented the cost of this SaMS. We recognized that software-based technologies, like those described by CPT codes 0697T and 0698T, are unique and rapidly evolving and that a significant fluctuation in payment may hinder patient access to these new services. For CY 2026, we finalized continuing to assign CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 ($900–$1,000)) with a payment of $950.50 which we believe best reflected the cost of the service at the time.

For CY 2027, we propose to identify the CoverScan procedure as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT codes 0697T and 0698T using our authority under section 1833(t)(2)(E). By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignment for CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment rate of $950.50. Additionally, we propose to assign CPT codes 0697T and 0698T to proposed new status indicator ''O1'' to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(5) Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP, a software-based service with algorithmic analysis. The service performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. In accordance with our SaaS add-on codes policy [25] (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Consistent with our SaaS add-on codes policy, CPT code 0724T, the add-on code for QMRCP is assigned to the identical APC and status indicator as CPT code 0723T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 ($900–$1,000)). For CY 2025, we continued to assign CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 ($900–$1,000)) based on there being fewer than 10 claims in the 4-year lookback period and the exception from the universal low- volume APC policy.

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. There were only four new claims for HCPCS code 0724T and no claims for CPT code 0723T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period due to an exception from the universal low-volume APC policy, we proposed, for CY 2026, to continue to assign CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 ($901–$1000)), with a payment rate of $950.50.

For CY 2027, we propose to designate the QMRCP procedure as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignments for CPT codes 0723T and 0724T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignments for CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 ($901–$1000) with a payment

[24] We note that when the add-on code policy was created in the CY 2023 OPPS/ASC final rule with comment period, we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

[25] We note that when the add-on code policy was created in the CY 2023 OPPS/ASC final rule with comment period, we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

rate of $950.50. Additionally, we propose to assign CPT codes 0723T and 0724T to proposed new status indicator ''O1'' to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(6) Fibresolve, 0877T and 0878T (APC 1508)

Effective July 1, 2024, the AMA CPT Editorial Panel established the following CPT codes to describe the software-based service with algorithmic analysis medical technology used for the non-invasive assessment of interstitial lung disease and idiopathic pulmonary fibrosis utilizing data from chest computed tomography (CT) images. The CPT codes, their long descriptors, and their current payment assignments are listed below that describe Fibresolve.

- 0877T—Augmentative analysis of chest CT imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging. CPT code 0877T is assigned to New Technology APC 1508 New Technology—Level 8 ($601–$700) and a status indicator of ''S'' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS) with a payment of $650.50.
- 0878T—Augmentative analysis of chest CT imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure. CPT code 0878T is assigned to New Technology APC 1508 New Technology—Level 8 ($601–$700) and a status indicator of ''S'' (Procedure or Service, Not Discounted When Multiple; Paid under OPPS) with a payment of $650.50.

For CY 2027, we propose to designate the Fibresolve procedure as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignments for CPT codes 0877T and 0878T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignments for CPT codes 0877T and 0878T to APC 1508 (New Technology—Level 8 ($601–$700) with a payment rate of $650.50. Additionally, we propose to assign CPT codes 0877T and 0878T to proposed new status indicator ''O1'' to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

D. Proposed Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2026 OPPS/ASC proposed rule, CY 2024 claims were generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2024 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the CY 2027 OPPS/ASC proposed rule, we proposed to designate five brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. The five brachytherapy APCs and four clinical APCs meet our criteria of having fewer than 100 single claims in the claims' year used for ratesetting (CY 2025 for the CY 2027 OPPS/ASC proposed rule). Nine of the 10 APCs were designated as low volume APCs in CY 2025. Based on data for the CY 2026 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) has 87 single claims and now meets our criteria to be designated as a low volume APC. Table 23 includes the CY 2025 claims available for ratesetting for each of the APCs we propose to designate as a low volume APC for CY 2027. The proposed cost statistics for our CY 2027 low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this proposed rule on the CMS website. We refer readers to our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices;* click on the relevant regulation to download the low volume APC cost statistics under the comprehensive (OPPS) ratesetting methodology in the downloads section of the web page.

TABLE 23: PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2027

APC	APC Description	CY 2025 Claims Available for Ratesetting
2635	Brachytx, non-str, HA, p-103	28
2642	Brachytx, stranded, c-131	41
2643	Brachytx, non-stranded, c-131	78
2645	Brachytx, non-stranded, gold-198	87
2647	Brachytx, NS, Non-HDRIr-192	13
5244	Level 4 Blood Product Exchanges and Related Services	40
5495	Level 5 Intraocular Procedures	94
5496	Level 6 Intraocular Procedures	35
5881	Ancillary Outpatient Services When Patient Dies	34

E. Proposed APC-Specific Policies

1. Nuclear Medicine and Related Services APC Series (APC 5591 Through 5594)

The Nuclear Medicine and Related Services APC series was created as part of the broader APC restructuring and consolidation in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70392 through 70397). The APC series was developed from what were previously separate APC groupings primarily organized by anatomy and imaging modality. Since the initial establishment of the Nuclear Medicine and Related Services series in the CY 2016 OPPS/ASC final rule with comment period, we have maintained the four-level APC structure for the series.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy of paying separately for diagnostic radiopharmaceuticals with estimated per day costs higher than a packaging threshold specific to diagnostic radiopharmaceuticals (89 FR 93948 through 93963). Because certain diagnostic radiopharmaceuticals are paid separately under the policy, the nuclear medicine and other services these diagnostic radiopharmaceuticals would otherwise be packaged into would no longer include those costs. As a result, based on the associated changes to the ratesetting process, we observed impacts on the estimated cost of services assigned to the Nuclear Medicine and Related Services APC series such that the range of cost significant codes across the various APC levels became less distinct, in particular between Levels 3 and 4.

As part of our standard process of reviewing updated claims and cost report data, we continue to observe in the CY 2027 OPPS data that the differences between the four levels of APC geometric means are less distinct then they were previously, in part due to the policy of paying separately for diagnostic radiopharmaceuticals. Specifically, under a four level APC structure using the NPRM claims data and maintaining the same APC assignments as in the CY 2026 OPPS/ASC final rule with comment period, the geometric mean cost of the Level 3 APC would be $1,367.99 while the geometric mean cost of the Level 4 APC would be $1,497.06. The range of cost significant codes in the Level 3 APC would be from $812 to $1,404, while the range for the Level 4 APC would be from $1,024 to $1,676; indicating a high degree of overlap in the estimated costs of the services assigned to those APC levels. Given the relative proximity of the APC geometric mean costs and the clinical and cost similarities of the services between the APCs in the Nuclear Medicine and Related Services series, we believe that it is appropriate to reorganize the Nuclear Medicine and Related Services APC series for the CY 2027 OPPS.

Additionally, we note that CPT codes 78431 (Myocardial imaging, positron emission tomography (pet), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan), 78432 (Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (*e.g.,* myocardial viability);), and 78433 (Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (*e.g.,* myocardial viability); with concurrently acquired computed tomography transmission scan) have sufficient CY 2025 claims data available to be appropriate assigned to clinical APCs for CY 2027 OPPS ratesetting. We believe the restructuring of the series now makes it appropriate to propose to assign these codes to APC 5594 (Level 4 Nuclear Medicine and Related Services) and we propose to assign these three CPT codes to APC 5594 for CY 2027.

Based on our review of the updated claims data, we propose to reassign a number of services to revised levels in the Nuclear Medicine and Related Services APC series for CY 2027 and to assign CPT codes 78431, 78432, and 78433 to APC 5594 (Level 4 Nuclear Medicine and Related Services) in the CY 2027 OPPS. Please see the APC-sorted Two Times Listing for this proposed rule on the CMS website or Addendum B to this proposed rule to see the Nuclear Medicine APC we have proposed to assign each HCPCS code in the series.

2. Breast/Lymphatic Surgery and Related Procedures APC Series (APC 5091 Through 5093)

The Breast/Lymphatic Surgery and Related Procedures APC series was initially created as part of the broader APC restructuring and consolidation in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70379 through 70380). The APC series was reorganized

from what were previously separate APC groupings for breast and skin surgery. In the CY 2017 OPPS/ASC final rule with comment period, we created an additional level 4 APC to the Breast/Lymphatic Surgery and Related Procedures APC series (81 FR 79584). Since that time, we have maintained the four-level APC structure for the series.

In the CY 2026 OPPS/ASC final rule with comment period, we observed that certain complexity adjustments in the APC series were being promoted up by two APC levels (90 FR 53466) due to cost inversion between the Level 2 and 3 APCs. This data anomaly occurred as a combined result of the APC levels having cost ranges that were not sufficiently distinct, and the contribution of the complexity adjustment claims data contributing to the APC geometric means. In the CY 2026 OPPS/ASC final rule with comment period, we were able to recalibrate the APCs to address these concerns, and, as part of our standard practice, would continue to monitor the claims data as available.

In reviewing the claims data available for ratesetting for the CY 2027 OPPS proposed rule, we continue to observe data anomalies due to the APC cost ranges not being sufficiently distinct, in particular between the Level 2 and 3 APCs for the Breast/Lymphatic Surgery and Related Procedures APC series. While APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures) has a cost significant range from approximately $7,131.27 to $8,734.72, the single cost significant code currently assigned to the Level 3 APC, that is not a complexity adjustment, has an estimated geometric mean cost of $8,219.71, falling well within the Level 2 cost significant range. As a result of the cost ranges overlapping and based on the cost and payment anomalies that would otherwise occur as a result, we believe that it is appropriate to consolidate the current Level 2 and 3 APCs in the Breast/Lymphatic Surgery and Related Procedures APC series into a single Level 2 APC. Accordingly, the current Level 4 Breast/Lymphatic Surgery and Related Procedures APC would then become the Level 3 Breast/Lymphatic Surgery and Related Procedures APC. We note that while there would be changes in the naming and structure of the levels, the APC geometric means, and resulting payment rates, would likely not be significantly different relative to where they otherwise would have been absent this proposal.

Based on our review of the updated claims data, for CY 2027, we propose to establish a 3 level Breast/Lymphatic Surgery and Related Procedures APC series by consolidating the current Level 2 and 3 APCs into a single Level 2 APC, and remapping the current Level 4 APC as the level 3 APC.

Please see the APC-sorted Two Times Listing for this proposed rule on the CMS website, or Addendum B to this proposed rule, to see the reconfigured Breast/Lymphatic Surgery and Related Procedures APC series and the APC placement and payment rate for each HCPCS code within the reconfigured APC series.

3. Hypoglossal Nerve Neurostimulator (HGNS) Procedures (APCs 5465, 5463, and 5432)

Effective January 1, 2022, the AMA's CPT Editorial Panel created three new codes to describe the open implantation of hypoglossal nerve neurostimulator (HGNS) array with an implanted pulse generator and a separate distal respiratory sensor, the revision or replacement of the HGNS, and the removal of the HGNS for the treatment of obstructive sleep apnea (OSA). The codes, their long descriptors, and APC and status indicators are listed below.

- 64582—*Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array.* CPT code 64582 is assigned to APC 5465 (Level 5 Neurostimulator and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).
- 64583—*Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator.* CPT code 64583 is assigned to APC 5463 (Level 3 Neurostimulator and Related Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC).
- 64584—*Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array.* CPT code 64584 is assigned to APC 5432 (Level 2 Nerve Procedures) and status indicator ''Q2'' (T-Packaged Codes).

As the technology has evolved, we realize that the current HGNS CPT codes do not accurately describe newer hypoglossal nerve neurostimulators that are on the market. As a result, some providers are utilizing CPT code 64568 (Open implantation of cranial nerve (*e.g.,* vagus nerve) neurostimulator electrode array and pulse generator) to describe the implantation of hypoglossal nerve neurostimulators that are not described by the current hypoglossal nerve neurostimulator implantation code.

To address the questions and concerns regarding coding and billing for the implantation, revision or replacement, or removal of hypoglossal nerve neurostimulators that are not described by existing coding, we created six new C-codes. These new C-codes describe the implantation, revision or replacement, and removal of hypoglossal nerve neurostimulators that do not contain a separate implantable respiratory sensor electrode or electrode array, and systems that do not contain an implanted battery or pulse generator. We used the current HGNS CPT codes as the crosswalk codes for the new C-codes. These new HCPCS codes and their APC and status indicator assignments were published in the April 2026 quarterly update CR (Transmittal 13686, Change Request 14380, dated March 13, 2026), and are retroactive to January 1, 2026. The proposed APC and status indicator assignments for HCPCS codes C8007–C8009 and C8011–C8013, along with their long descriptors are shown in Table 24. The proposed CY 2027 rates for these codes can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 24: PROPOSED CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR THE HYPOGLOSSAL NERVE NEUROSTIMULATOR C-CODES

HCPCS Code	Long Descriptor	Proposed CY 2027 OPPS SI	Proposed CY 2027 OPPS APC
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array	J1	5465
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator.	J1	5463
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator.	Q2	5432
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components.	J1	5465
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver.	J1	5463
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and Receiver.	Q2	5432

4. Permanent Prostatic Urethral Stent, CPT Code 52282 (APC 5375)

The ProVee® System is indicated to treat obstructive lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) in men with prostatic urethral lengths greater than or equal to 3.75 cm and prostatic volumes between 30 cc and 80 cc. The insertion of a permanent prostatic urethral stent procedure, represented by CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent), became effective January 1, 1998, and describes the insertion of a permanent urethra stent using an endoscope. This procedure offers another therapy option for select patients with lower urinary tract symptoms (LUTS) secondary to BPH.

For CY 2026, we assigned CPT code 52282 to APC 5374 (Level 4 Urology and Related Services) with a payment rate of $3,601.33 based on its geometric mean cost of approximately $3,775, which was calculated using the available 115 single frequency claims from the CY 2024 claims data.

For this CY 2027 OPPS/ASC proposed rule, we reviewed the CY 2025 claims submitted between January 1, 2025 through December 31, 2025, that were processed on or before December 31, 2025, for CPT code 52282 and found 109 single frequency claims available for ratesetting, with a resulting geometric mean cost of $4,005. Additionally, for this CY 2027 OPPS/ASC proposed rule, we examined the claims reported for CPT code 52282. We noted that there has not been an FDA approved permanent prostatic urethral stent on the US market for approximately 9 years until a permanent prostatic urethral stent received their FDA PMA approval in late 2025. Therefore, we believe the report claims for CPT code 52282 do not accurately represent the device and service cost associated with inserting a permanent prostatic urethral stent. Based on our examination of device and service costs associated with a permanent prostatic urethral stent, we believe it is appropriate to move CPT code 52282 to APC 5375 (Level 5 Urology and Related Services) from APC 5374 (Level 4 Urology and Related Services) because CPT code 52282 shares more resource cost and clinical homogeneity with procedures in APC 5375. Specifically, we believe CPT code 52282 shares resource and clinical homogeneity with HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants). Therefore, for CY 2027, we propose to reassign CPT code 52282 from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services).

5. Integrated Sacral Neurostimulator, CPT Code 0786T (APC 5464)

Effective January 1, 2024, the CPT Editorial Panel separated integrated from non-integrated (*i.e.,* traditional) sacral neurostimulator procedures by establishing new CPT code, 0786T to report procedures using integrated sacral neurostimulator devices, while CPT code 64590 was updated to reflect the use of traditional technology. We assigned CPT code 0786T to status indicator ''E1'' (Not covered by any outpatient benefit category) because the device associated with this CPT code did not have FDA approval. The long descriptors for CPT codes 0786T and 64590 are listed below:

- 0786T—*Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed.*
- 64590—*Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver.*

On June 17, 2025, Neuspera received FDA approval for their implanted sacral neurostimulator for urge urinary incontinence (UUI). At the August 2025 HOP Panel meeting, the manufacturer requested that we assign CPT code 0786T to APC 5464 (Level 4 Neurostimulator and Related

Procedures). The HOP Panel agreed with the presenter and made that recommendation.

In the CY 2026 OPPS/ASC final rule with comment period, we assigned CPT code 0786T to APC 5463 (Level 3 Neurostimulator and Related Procedures) and status indicator ''J1'' based on what we believed were the costs and resources required to perform the procedure with an integrated device.

For CY 2027, proposed OPPS payment rates are based on available CY 2025 claims data. Because 0786T was not assigned to a clinical APC before January 1, 2026, we do not have any claims data. Based on our examination of the procedures assigned to the Level 3 and Level 4 Neurostimulator and Related Procedures APCs, we believe it is appropriate to reassign CPT code 0786T from APC 5463 (Level 3 Neurostimulator and Related Procedures) to APC 5464 (Level 4 Neurostimulator and Related Procedures) because CPT code 0786T shares more resource cost and clinical homogeneity with procedures in APC 5464, specifically, with the other sacral and tibial neuromodulation procedures for bladder dysfunction that are assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). Therefore, for CY 2027, we propose to reassign CPT code 0786T from APC 5463 (Level 3 Neurostimulator and Related Procedures) to APC 5464 (Level 4 Neurostimulator and Related Procedures). The proposed APC and status indicator assignment for CPT code 0786T is shown in Table 25. The proposed CY 2027 payment rates for CPT code 0786T can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 25: FINAL CY 2026 AND PROPOSED CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENT FOR THE INTEGRATED NEUROSTIMULATOR PROCEDURE

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed.	5463, J1	5464, J1

6. C-Codes Describing Percutaneous Coronary Intervention (PCI) With Drug-Eluting Stents, C-codes C9601, C9603, C9605, and C9608

Effective January 1, 2013, CMS created several HCPCS C-codes to describe certain percutaneous coronary intervention (PCI) procedures utilizing drug eluting stents to mirror those PCI CPT codes that do not utilize drug eluting stents. The AMA CPT Editorial Board deleted several of those CPT codes effective January 1, 2026. For CY 2027, we propose to delete the C-codes that mirrored the deleted CPT codes, specifically revising the status indicators for C9601, C9603, C9605, and C9608 to ''D'' (Discontinued Codes) indicating that they are no longer active codes. The C-codes, long descriptors, status indicators, and their corresponding CPT code (listed below each C-code) are shown in Table 26.

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TABLE 26: FINAL CY 2026 AND PROPOSED CY 2027 STATUS INDICATOR REVISIONS FOR C9601, C9603, C9605, C9608

HCPCS Code (Corresponding CPT Code)	Long Descriptor	Final CY 2026 SI	Proposed CY 2027 SI
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N	D
(92929)	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	D	N/A
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N	D
(92934)	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	D	N/A
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N	D
(92938)	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	D	N/A
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N	D

HCPCS Code (Corresponding CPT Code)	Long Descriptor	Final CY 2026 SI	Proposed CY 2027 SI
(92944)	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	D	N/A

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7. Electrophysiologic Evaluation of Cardiac Contractility Modulation Systems, CPT Code 0930T

CPT code 0930T (*Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator*) became effective January 1, 2025 and is used to describe the electrophysiologic evaluation of a cardiac contractility modulation system at the time of initial implantation or replacement of the system. This code is currently assigned to APC 5211 (Level 1 Electrophysiologic Procedures) and status indicator ''J1'' (Hospital Part B Services Paid Through a Comprehensive APC). There are currently no claims data for CPT 0930T.

After review of the service and other like services, we believe this service is always performed with the initial implantation or replacement of the system and therefore, we believe that the electrophysiologic evaluation is integral, ancillary, supportive, dependent, and adjunctive to the primary service (the implantation or replacement of the system) and should therefore be packaged into the CPT code describing the initial implantation or replacement of the cardiac contractility modulation-defibrillator pulse generator.

Therefore, for CY 2027, we propose to revise the status indicator for CPT 0930T to ''N''. The proposed status indicator assignment for CPT code 0930T is shown in Table 27. The proposed CY 2027 payment rate for this HCPCS code can be found in Addendum B to the CY 2027 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 27: FINAL CY 2026 AND PROPOSED CY 2027 STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0930T

CPT Code	Long Descriptor	Final CY 2026 APC, SI	Proposed CY 2027 SI
0930T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator	5211, J1	N

8. Endovenous Femoral-Popliteal Arterial Revascularization With Placement of Stent Graft, CPT Code 0505T

CPT code 0505T *(Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion)* became effective January 1, 2018 and is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening ischemia.

The DETOUR™ System is a graft system used with the service described by CPT 0505T. It restores arterial blood flow to the lower limb around the blocked femoral artery and allows for venous return, which reduces the signs and symptoms of lower limb ischemia and prevents amputation. We created HCPCS code C1604 *(Graft, transmural transvenous arterial bypass (implantable), with all delivery system components)* when the DETOUR™ System was approved for transitional device pass-through payment under OPPS effective January 1, 2024. The pass-through payment for this device

expires December 31, 2026. Once the pass-through payment period expires, payment for the device is packaged into the OPPS payment rate for the associated procedure(s).

We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data and review of the clinical characteristics of the procedure. For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. CPT code 0505T is currently assigned to APC 5193 (Level 3 Endovascular Procedures) with a payment of approximately $11,800. We note that CPT code 0505T has a geometric mean cost (GMC) of $41,123 based on 46 single frequency claims. We considered reassigning CPT 0505T to APC 5194 (Level 4 Endovascular Procedures) with a payment of approximately $18,700 but we do not believe this APC is appropriate after incorporating the costs of the expiring pass-through device. Given the low volume of claims data for this procedure and the absence of a clinical APC in terms of clinical and resource similarity, we propose to reassign CPT 0505T to APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment of $45,000.50. As we continue to gather adequate claims data on this code, we invite public comment on the appropriate clinical APC for CPT code 0505T.

Please refer to Table 28 for the proposed APC and status indicator assignment for CPT code 0505T. The proposed payment rate for this HCPCS code can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 28: FINAL CY 2026 AND PROPOSED CY 2027 STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0505T

CPT Code	Long Descriptor	Final CY 2026 APC, SI	Proposed CY 2027 APC, SI
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	5193, J1	1580, S

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, OPPS transitional pass-through payment status for a device category are limited to a period of not less than 2 years but not more than 3 years.

In the CY 2017 OPPS/ASC final rule with comment period, in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category (81 FR 79654). In addition, in the CY 2017 OPPS/ASC final rule with comment period, we finalized a policy to allow for quarterly expiration of pass-through payment status for devices to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices (81 FR 79655). We also established a policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763). We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.[26]

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, 21 device categories are eligible for pass-through payment. These devices are listed in Table 29 where we detail the expiration dates of pass-through payment status for each of the 21 devices currently receiving device pass-through payment.

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[26] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This collection (CMS–10052) has an OMB control number of 0938–0857 and an expiration date of June 30, 2029.

TABLE 29: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2026, IN 2027, IN 2028, OR IN 2029

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (*i.e.* disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (*i.e.* disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	09/30/2027
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components	01/01/2025	12/31/2027
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components	01/01/2025	12/31/2027
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)	01/01/2025	12/31/2027
C1738	Powered, single-use (i.e. disposable) endoscopic ultrasound-guided biopsy device	01/01/2025	12/31/2027
C1739	Tissue marker, uniquely detectable and identifiable with probe/sensor, any method (implantable), with delivery system	01/01/2025	12/31/2027
C9610	Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)	01/01/2025	12/31/2027

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1740	Leadless electrode, transmitter, battery (all implantable), for sequential left ventricular pacing	10/01/2025	09/30/2028
C1741	Anchor/screw for bone fixation, absorbable (implantable)	10/01/2025	09/30/2028
C1742	Pressure monitoring system, compartmental intramuscular (implantable), continuous, including all components (e.g., introducer, sensor), excludes mobile (wireless) software application	10/01/2025	09/30/2028
C1607	Neurostimulator, integrated (implantable), rechargeable with all implantable and external components including charging system	01/01/2026	12/31/2028
C1608	Prosthesis, total, dual mobility, first carpometacarpal joint (implantable)	01/01/2026	12/31/2028
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)	04/01/2026	03/31/2029
C1609	Vertebral device, motion-preserving, with screw fixation	07/01/2026	06/30/2029

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2. New Device Pass-Through Applications for CY 2027

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories to determine the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we continue to believe that pass-through payments for devices that offer substantial clinical improvement are important to ensure hospitals can provide Medicare beneficiaries with access to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

As finalized in CY 2026 OPPS/ASC final rule with comment period, skin substitutes with an approved Biologics License Application (BLA) will be considered under transitional drug pass-through payment status, and skin substitutes with FDA Premarket approval (PMA) or FDA 510(k) clearance will continue to be evaluated under transitional device pass-through payment status (90 FR 53636).

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, under § 419.66(c), to determine whether a new category of pass-through payment devices should be established.

The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)).

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. We generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test (69 FR 65775), and we calculate the device offset amount at the HCPCS/CPT code level (81 FR 79657); and

- Demonstrate a substantial clinical improvement, that is, the device to be included in the category has demonstrated that it will 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, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

In the CY 2016 OPPS/ASC final rule, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications preliminarily approved during quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while applicants whose submissions are not approved during quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2023 OPPS/ASC final rule, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 OPPS/ASC proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

In the CY 2020 OPPS/ASC final rule with comment period, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19457 to 19459), we have proposed 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 the same eligibility requirements to receive add-on payments and/or pass-through payments. Specifically, we proposed 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 proposed to revise paragraph § 419.66(c)(2)(ii) to reflect this proposed policy. If finalized as proposed, the change would go into effect on October 1, 2026 (91 FR 19458).

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html, in the ''Downloads'' section.

b. Applications Received for Device Pass-Through Status for CY 2027

We received 19 applications by the March 2, 2026, quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2027 OPPS/ASC proposed rule. Six applications subsequently withdrew. Discussions of the 13 complete applications, 10 under alternative pathway and 3 under traditional pathway, we received by the March 2, 2026 deadline are included following section IV.2.b. of this proposed rule. Of the applications, we received five in the second quarter of 2025, eight in the third quarter of 2025, one in the fourth quarter of 2025, and five in the first quarter of 2026. Seven of the applications were preliminarily approved for device pass-through payment status during the quarterly review process: The MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Esprit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System.

Applications received after the March 2026 deadline for the remaining 2027 quarters (the quarters beginning June 1, September 1, and December 1 of 2026) through March 1, 2027, if any, will be discussed in the CY 2028 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.*

(1) Alternative Pathway Device Pass-Through Applications

We received 10 device pass-through applications by the March 2026 application deadline for devices that were eligible to apply under the alternative pathway.

(a) Altius® Direct Electrical Nerve Stimulation System

Neuros® Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Altius® Direct Electrical Nerve Stimulation System (the Altius® System) for CY 2027. According to the applicant, the Altius® System is an implantable neuromodulation system that provides continuous, high frequency, high amplitude nerve stimulation to either the sciatic nerve or both the tibial and common peroneal nerves by directly stimulating targeted nerves via implanted cuff electrode leads that are wrapped circumferentially around target nerves in the amputated leg. The applicant stated that the Altius® System consists of the (1) Altius® Implantable Pulse Generator (IPG), which is implanted in the abdomen; (2) Altius® Cuff Electrode Leads; (3) Altius® Battery Charger and alternating current (AC) adapter; (4) Altius® Patient Controller, which allows the patient to activate the IPG to initiate therapy; (5) Programming Wand, which is used by the provider to program and set stimulus therapy parameters; and (6) Programmer Application Personal Computer (PAPC), which includes physician programming software. The applicant is seeking a new device category for transitional pass-through payment status for only the Altius® IPG and the Altius® Cuff Electrode Lead components of the Altius® System. The applicant stated that the Altius® IPG is a rechargeable neurotransmitter device that is implanted in the abdomen and when activated, generates a continuous high frequency, high amplitude alternating current electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s). Per the applicant the ''alternating'' nature of the delivered electrical stimulus refers to the direct electrical stimulation of the circumferential electrodes within a lead distributed in an alternating fashion across these electrodes.

Table 30 provides an overview of the transitional device pass-through payment status application for the Altius® System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250530FMCYD.*

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[27] The applicant conducted cost calculations for both the Altiusr IPG with one Altiusr Cuff Electrode Lead ($41,000.00) and the Altiusr IPG with two Altiusr Cuff Electrode Leads ($52,000.00). We consider both costs as the estimated reasonable cost to assess whether the Altiusr System meets the cost significance requirements.

TABLE 30: ALTIUS® SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* PMA approval - August 26, 2024 *Application submitted to CMS:* May 30, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* Altius® System is an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. *Breakthrough Device designation:* Altius® System is an aid in the management of chronic intractable pain of the lower limb of adult amputees. This device received FDA Breakthrough Device designation under the trade name Altius® High Frequency Nerve Block System. The trade name was later updated to the Altius® Direct Electrical Nerve Stimulation System.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is surgically implanted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1778 (Lead, neurostimulator (implantable)), C1767 (Generator, neurostimulator (implantable), non-rechargeable), C1787 (Patient programmer, neurostimulator), C1816 (Receiver and/or transmitter, neurostimulator (implantable)), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads), C1825 (Generator, neurostimulator (implantable), non-rechargeable, with carotid sinus baroreceptor stimulation lead(s)), C1826 (Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system), C1827 (Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller), and C1883 (Adapter/extension, pacing lead or neurostimulator lead (implantable) do not describe the device.	See following discussion.
Cost Criteria	The cost for eligible device components of Altius® System (the Altius® IPG and Altius® Cuff Electrode Lead(s)) is $41,000.00 or $52,000.00, depending on whether the patient requires one or two cuff electrodes.[26] The cost of the Altius® IPG is $30,000.00 and the cost of each Altius® Cuff Electrode Lead is $11,000.00. For cost significance requirements:[27] HCPCS code: 64575 APC code: 5463 CY 2026 device offset amount: $7,697.89 CY 2026 APC payment rate: $11,384.04 The Altius® IPG with one Altius® Cuff Electrode Lead:	No concerns.
	Requirement #1: ($41,000.00 / $11,384.04) x 100 = 360.15%. Requirement #2: ($41,000.00 / $7,697.89) x 100 = 532.61% Requirement #3: (($41,000.00 - $7,697.89) / $11,384.04) x 100 = 292.53% The Altius® IPG with two Altius® Cuff Electrode Leads: Requirement #1: ($52,000.00 / $11,384.04) x 100 = 456.78%. Requirement #2: ($52,000.00 / $7,697.89) x 100 = 675.51% Requirement #3: (($52,000.00 - $7,697.89) / $11,384.04) x 100 = 389.16%	

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We are inviting public comment on whether the Altius® System meets the newness criterion at § 419.66(b)(1) and whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the eligibility criteria at § 419.66(b)(3) and (b)(4).[28]

Regarding the device category eligibility criterion at § 419.66(c)(1), with respect to the Altius® IPG and Altius® Cuff Electrode Lead components, the applicant stated that no existing (current or previous) device pass-through payment categories appropriately describe the nominated device components. Per the applicant, the existing pass-through codes C1778 (Lead, neurostimulator (implantable)) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system) do not describe the Altius® IPG and the Altius® Cuff Electrode Lead components because these codes (1) are not specifically indicated for treating chronic intractable lower limb amputation pain; (2) are not capable of delivering continuous, high amplitude, high frequency alternating current; (3) do not use circumferentially wrapped and anchored cuff electrode leads to provide direct energy delivery to the targeted nerves; and (4) do not allow for physician-pre-programmed therapy delivery controlled by the patient using the patient stimulation controller. The applicant also stated that devices described by C1778 do not make direct contact with the target nerve; instead they deliver stimulation to the general region of the pain, unlike the Altius® Cuff Electrode Leads. The applicant added that existing devices described by C1822 deliver low-amplitude, rectangular pulses per second to general or peripheral areas to increase nerve activity and produce pain relief, whereas the Altius® IPG provides continuous, high-amplitude sinusoidal waveform stimulation to decrease target nerve activity and produce on-demand pain relief. The applicant asserted that the Altius® System, including the Altius® IPG and Altius® Cuff Electrode Lead components, is the only FDA-authorized neuromodulation system indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees.

Based on the description the applicant provided, the Altius® IPG is a rechargeable neurotransmitter device that generates a continuous high frequency, high amplitude alternating electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s), and therefore, could be appropriately described by C1778 (Lead, neurostimulator (implantable) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), respectively. Specifically, we believe that the pass-through payment category C1778 may appropriately describe the Altius® Cuff Electrode Lead component because the pass-through payment category describes any device that is an implantable neurostimulator lead. Additionally, we believe the pass-through payment category C1822 may appropriately describe the Altius® IPG because the category includes implantable neurostimulator pulse generators that deliver high-frequency stimulation (including approximately 10 kHz) and are rechargeable using an external charging system. Further, C1822 does not describe the amplitude, pulse frequency, or waveform of the stimulation generated by the device. We note that CMS does not establish pass-through device categories for the purpose of describing specific devices, but rather, device categories are intended to encompass all devices that can be appropriately described by a category. In this context, we believe the Altius® IPG and the Altius® Cuff Electrode Lead components may be appropriately described by C1778 and C1822.

We are inviting public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criterion at § 419.66(c)(1).

We are also inviting public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components for CY 2027.

(b) Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

Abbott Laboratories submitted an application for a new device category for transitional pass-through payment status for the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK) for CY 2027. According to the applicant, the Esprit™ BTK is a temporary, balloon-expandable resorbable polymer scaffold with a drug (everolimus) and resorbable polymeric coating, delivered via a balloon dilatation catheter, that is designed to resorb over time and is intended to improve luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia.

Table 31 provides an overview of the transitional device pass-through payment status application for the Esprit™ BTK and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250829XYFGP.*

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[28] For its cost calculations, the applicant selected HCPCS code 64590 in APC 5464 and based its calculations on CY 2026 data. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). For our calculations, we used APC 5463, which we believe has the lowest applicable APC payment rate ($11,384.04) related to the HCPCS codes provided by the applicant, and HCPCS code 64575 in APC 5463, which has a device offset amount of $7,697.89, at the time the application was received. Based on our initial assessment for this proposed rule, using the APC payment rate of $11,384.04 and the device offset amount of $7,697.89, we believe the Altiusr System meets the cost significance requirements.

TABLE 31: ESPRIT™ BTK APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* Premarket Approval (PMA) - April 26, 2024 *Application submitted to CMS:* August 29, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with Chronic Limb Threatening Ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm. *Breakthrough Device Designation Indication:* The Absorb GT1 BVS is a temporary scaffold that will fully resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with critical limb ischemia (CLI). In all cases, the treated lesion length should be less than the total scaffolding length with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm. Note: This device received FDA Breakthrough Device designation through the Expedited Access Pathway (EAP) on June 28, 2017, under the trade name Absorb GT1 BVS System. The trade name was later updated to Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit ™ BTK System).	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically implanted in a patient's infrapopliteal artery.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1874 (Stent, coated/covered, with delivery system), C1875 (Stent, coated/covered, without delivery system), C1876 (Stent, non-coated/non-covered, with delivery system), C1877 (Stent, non-coated/non-covered, without delivery system), C2625 (Stent, non-coronary, temporary with delivery system), and C2617 (Stent, non-coronary, temporary without delivery system) do not describe the Esprit™ BTK.	No concerns.
Cost Criteria	The cost of the Esprit™ BTK is $10,650.00. Per the applicant, the Esprit™ BTK includes two one-time-use individual components: Esprit™ BTK scaffold and Esprit™ BTK delivery system. The cost of each Esprit™ BTK is $3000.00. A range of one to six scaffolds are implanted depending on the length of the lesion being treated and the corresponding healthy-to-healthy clinical need of the patient, with an average of 3.55 scaffolds used per case. Therefore, the average cost per case is $10,650. For cost significance requirements: HCPCS code: 37284 APC code: 5194 CY 2026 device offset amount: $8,208.78 CY 2026 APC payment rate: $18,728.69 Requirement #1: ($10,650.00 / $18,728.69) x 100 = 56.86%. Requirement #2: ($10,650.00 / $8,208.78) x 100 = 129.74%. Requirement #3: (($10,650.00 - $8,208.78) / $18,728.69) x 100 = 13.03%.	No concerns.

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The Esprit™ BTK was preliminarily approved for device pass-through payment status effective April 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the Esprit™ BTK under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the Esprit™ BTK meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the Esprit™ BTK for device pass-through payment status for CY 2027.

(c) MY01 Continuous Compartmental Pressure Monitor

MY01 Inc. submitted an application for a new device category for transitional pass-through payment status for the MY01 Continuous Compartmental Pressure Monitor for CY 2027. According to the applicant, the MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure to aid in the diagnosis of acute and chronic compartment syndrome. The nominated device consists of an introducer and a pressure monitor which are used in conjunction with the MY01 Mobile Application. The applicant stated that it is only seeking a new device category for transitional pass-through payment status for the MY01 Continuous Compartmental Pressure Monitor component.

Table 32 provides an overview of the transitional device pass-through payment status application for the MY01 Continuous Compartmental Pressure Monitor and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250602XAAW9.*

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TABLE 32: MY01 CONTINUOUS COMPARTMENTAL PRESSURE MONITOR APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - March 13, 2025 *Application submitted to CMS:* June 2, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments. *Breakthrough Device designation:* (June 20, 2021) The MY01 device is used for real-time and continuous measurement of muscle pressures. The measured muscle pressure can be used as an aid in the diagnosis of acute compartment syndrome (ACS). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically inserted into the muscle compartment for continuous pressure monitoring.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	No similar device category codes.	No concerns.
Cost Criteria	The cost of the MY01 Continuous Compartmental Pressure Monitor is $3,250.00. Per the applicant, the MY01 Mobile Application (included in the system) is available to be downloaded and accessed free of charge with the corresponding MY01 Continuous Compartmental Pressure Monitor. For cost significance requirements: HCPCS code: 20950 APC code: 5071 CY 2025 device offset amount: $0.00 CY 2025 APC payment rate: $703.59 Requirement #1: ($3,250.00 / $703.59) x 100 = 461.02%. Requirement #2: $3,250.00 exceeds $0.00 by at least 25%. Requirement #3: (($3,250.00 - $0.00) / $703.59) x 100 = 461.02%.	No concerns.

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The MY01 Continuous Compartmental Pressure Monitor was preliminarily approved for device pass-through payment status effective October 1, 2025. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the MY01 Continuous Compartmental Pressure Monitor under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the MY01 Continuous Compartmental Pressure Monitor meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the MY01 Continuous Compartmental Pressure Monitor for device pass-through payment status for CY 2027.

(d) ProSense® Cryoablation System

IceCure™ Medical Ltd. submitted an application for a new device category for transitional pass-through payment status for the ProSense® Cryoablation System for CY 2027. According to the applicant, the ProSense® Cryoablation System is designed to destroy tissue by the application of extreme cold temperatures utilizing liquid nitrogen for the treatment of breast cancer for patients with low-risk tumors. The applicant stated that the ProSense® Cryoablation System is comprised of (1) the ProSense® Chassis, (2) an adjustable touch screen, and (3) external accessories, including introducers, liquid nitrogen dewar, holder, foot pedal, and Prosense® Cryoprobes. The applicant is seeking a new device category for transitional pass-through payment status for only the ProSense® Cryoprobe component of the ProSense® Cryoablation System. Per the applicant, the ProSense® Cryoprobe is a rigid probe with a tip that creates ice balls to destroy target tissue through cycles of freezing and thawing.

Table 33 provides an overview of the transitional pass-through payment status application for the ProSense® Cryoablation System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP251226K6A1C.*

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TABLE 33: PROSENSE® CRYOABLATION SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* De Novo authorization - October 3, 2025 *Application submitted to CMS:* December 26, 2025	See following discussion.
Breakthrough Device Designation	*FDA Indication:* The ProSense® Cryoablation System is indicated for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy, including patients not suitable for surgery for breast cancer treatment. Biologically low-risk breast cancer is defined as unifocal tumor, size ≤1.5 cm, estrogen receptor (ER)-positive, progesterone receptor (PR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Ki-67<15%, and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0). *Breakthrough Device designation:* The IceCure ProSense® Cryoablation System is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ear, nose, and throat (ENT), gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including breast cancer, prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications: • Urology (ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH). • Oncology (ablation of cancerous or malignant tissue and benign tumors and palliative intervention). • Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions). • Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia). ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth). General Surgery (ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions. • Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions. Destruction of warts or lesions. Palliation of tumors of the oral cavity, rectum, and skin). • Thoracic Surgery (ablation of arrhythmic cardiac tissue and cancerous lesions). • Proctology (ablation of benign or malignant growths of the anus and rectum and hemorrhoids). • Breast Cancer: The ProSense® is indicated for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer.	No concerns.
§ 419.66(b)(3)	Device is single-use, is an integral part of the cryoablation procedure, is used in one patient only, is surgically inserted, and comes into contact with human tissue.	No concerns.
§ 419.66(b)(4)	Device is not equipment for which depreciation and financing expenses are recovered as depreciable assets and is not a supply furnished incident to the service.	No concerns.
Device Category	Device category code C2618 (Probe, cryoablation) does not describe the ProSense® Cryoprobe.	See following discussion.
Cost Criteria	The cost of the ProSense® Cryoprobe is $2,550.00. For cost significance requirements:	No concerns.

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
	HCPCS code: 0581T APC code: 5091 CY 2025 device offset amount: $1,816.99 CY 2025 APC payment rate: $3,829.28 Requirement #1: ($2,550.00 / $3,829.28) x 100 = 66.59%. Requirement #2: ($2,550.00/ $1,816.99) x 100 = 140.34%. Requirement #3: (($2,550.00 - $1,816.99) / $3,829.28) x 100 = 19.14%.	

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As stated previously, with respect to the newness criterion at § 419.66(b)(1), the device must have received FDA approval or clearance (that is, FDA marketing authorization), and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization. In the CY 2016 OPPS/ASC final rule with comment period, we clarified that we intended to convey that the 3-year timeframe for submitting a device pass-through payment application would be triggered by the initial FDA approval or clearance, and not by any subsequent FDA approvals or clearances. We specified ''initial'' FDA clearance or approval in § 419.66(b)(1) because, in some cases, FDA will provide supplemental approvals or clearances for a device after the initial approval or clearance (80 FR 70420). We received a pass-through payment status application for the ProSense® Cryoablation System on December 26, 2025, which we do not believe is within 3 years of the initial FDA marketing authorization.

The ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, was previously cleared on December 20, 2019, in K183213, the 510(k) clearance for the IceCure Family Cryoablation System (IceSense™3, ProSense®, MultiSense).[29] The predicate device described in K183213, the IceSense™3 System, was previously cleared on November 29, 2010, in K102360,[30] and the preceding predicate device, the Galil Medical SeedNet Family was cleared on November 18, 2005, in K052530.[31] We note that K183213 states that cryoablation is the fundamental technological principle for both the subject IceCure Family of cryotherapy devices and the predicate IceSense™3 System cleared in K102360 and the Galil Medical SeedNet Family cleared in K052530. Finally, according to K183213, the ProSense® Cryoablation System is a mere rebranding of the cleared IceSense™3 single-probe system cleared in K102360, and the ProSense® Cryoablation System has the same hardware and software components as the IceSense™3 System. K183213 also states that the hardware and software changes introduced since the device was originally cleared on November 29, 2010, in K102360, were analyzed and determined not to require new 510(k) premarket notifications and that the K183213 submission includes the current configuration of the system.

While the October 3, 2025, FDA decision summary for De Novo classification for the ProSense® Cryoablation System includes a new indication for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer, based on the information in K183213, we believe that the initial FDA marketing authorization date for the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe component, may be as early as November 18, 2005, or as recent as December 20, 2019. The applicant submitted the pass-through payment application on December 26, 2025, which is more than 3 years after either November 18, 2005, or December 20, 2019; therefore, we do not believe that the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe, meets the newness criterion.

We are inviting public comment on whether the ProSense® Cryoablation System meets the newness criterion at § 419.66(b)(1).

We also are inviting public comment on whether the ProSense® Cryoprobe meets the eligibility criteria at § 419.66(b)(3) and (b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), with respect to the ProSense® Cryoprobe, the applicant stated that the existing pass-through code C2618 (Probe, cryoablation) does not appropriately describe the ProSense® Cryoprobe. According to the applicant, the ProSense® Cryoprobe is currently included in this existing category only because that category is old, extremely broad, and does not allow for appropriate recognition of innovative new technologies or include those that have received FDA Breakthrough Device designation. The applicant also stated that since C2618 was established, CMS has created other categories for ablation catheters that are specific to use in specific anatomic locations, such as non-cardiac endovascular (C1888) and extravascular (C1886). Further, the applicant stated that the ProSense® Cryoprobe is the only device cleared under product code QXW as a cryoablation device for local low-risk breast cancer treatment.

Based on the description the applicant provided, the ProSense® Cryoprobe is a probe used for cryoablation, and therefore, could be appropriately described by C2618 (Probe, cryoablation). Specifically, we believe that the pass-through payment category C2618 may appropriately describe the ProSense® Cryoprobe because C2618 describes any probe used for cryoablation and is not specific to an anatomical location. We note that we do not establish pass-through device categories for the purpose of describing specific devices, rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we believe the ProSense® Cryoprobe may be appropriately described by C2618.

We are inviting public comment on whether the ProSense® Cryoprobe meets the device category eligibility criterion at § 419.66(c)(1).

We are also inviting public comment on whether the ProSense® Cryoprobe meets the cost criterion at § 419.66(d)(3).

[29] U.S. Food and Drug Administration. (2019, December 20). *Decision Summary for K183213 [IceCure Family Cryoablation System (IceSense™3, ProSense®, MultiSense)].* U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183213.pdf.*

[30] U.S. Food and Drug Administration. (2010, November 29). *510(k) Summary for K102360 [IceCure's IceSense™3 device].* U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/cdrh_docs/pdf10/K102360.pdf.*

[31] U.S. Food and Drug Administration. (2005, November 18). *510(k) Summary for K052530 [SeedNet Family].* U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/cdrh_docs/pdf5/K052530.pdf.*

After reviewing the information provided by the applicant, we are unable to determine that the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, meets the new device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, for CY 2027.

(e) RemeOs™ Screw LAG Solid

Bioretec, Inc. submitted an application for a new device category for transitional pass-through payment status for the RemeOs™ Screw LAG Solid for CY 2027. According to the applicant, the RemeOs™ Screw LAG Solid is an absorbable, magnesium-based alloy screw intended for the use in traumatic and orthopedic surgery for the fixation of bone fractures and for fixation after osteotomies, such as for the correction of deformities or malalignments. The absorbable implant provides temporary fixation and stabilization through osteosynthesis of bone fractures and osteotomies until bony fusion has occurred.

Table 34 provides an overview of the transitional device pass-through payment status application for the RemeOs™ Screw LAG Solid and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2506023YUR4.*

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TABLE 34: REMEOS™ SCREW LAG SOLID APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* De Novo classification - March 29, 2023 *Application submitted to CMS:* June 6, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The RemeOs™ Screw LAG Solid is intended for the use in traumatic and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and for the fixation after osteotomies, e.g., for the correction of deformities or malalignments. The absorbable implants serve as temporary fixation and stabilization by osteosynthesis of bone fractures and osteotomies until bony fusion has occurred. The RemeOs™ Screw LAG Solid is intended to be used for skeletally mature adults. The RemeOs™ Screw LAG Solid is indicated for the fixation of the medial malleolus. *Breakthrough Device designation:* (March 8, 2021) The RemeOs™ Screw LAG Solid products are intended for use in traumatic surgery/traumatology and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and osteotomies, and for the correction of deformities or malalignments. The implants serve as temporary fixation and stabilization by osteosynthesis of bones and fragments until bony fusion has occurred.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically inserted/implanted into the body for the fixation of bone fractures (osteosynthesis) and for fixation after osteotomies.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not describe the device.	No concerns.
Cost Criteria	The cost of the RemeOs™ Screw LAG Solid is $2,999.00. For cost significance requirements:[31] HCPCS code:27766 APC code: 5114 CY 2025 device offset amount: $1,639.49 CY 2025 APC payment rate: $7,143.73 Requirement #1: ($2,999.00 / $7,143.73) x 100 = 41.98%. Requirement #2: ($2,999.00 / $1,639.49) x 100 = 182.92%. Requirement #3: (($2,999.00 - $1,639.49) / $7,143.73) x 100 = 19.03%.	No concerns.

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The RemeOs™ Screw LAG Solid was preliminarily approved for device pass-through payment status effective October 1, 2025. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the RemeOs™ Screw LAG Solid under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing

authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the RemeOs™ Screw LAG Solid meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the RemeOs™ Screw LAG Solid for device pass-through payment status for CY 2027.

(f) SetPoint System

SetPoint Medical submitted an application for a new device category for transitional pass-through payment status for the SetPoint System for CY 2027. According to the applicant, the SetPoint System is a non-pharmacological treatment for rheumatoid arthritis (RA) and is a fully integrated neuroimmune modulation therapy for adults with moderately to severely active RA. The system consists of a rechargeable neuroimmune stimulator implanted on the left cervical vagus nerve during a 60–90-minute procedure which subsequently delivers one minute of stimulation per day to activate the body's innate neuroimmune pathway.

Table 35 provides an overview of the transitional device pass-through payment status application for the SetPoint System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2508042W2C1.*

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TABLE 35: SETPOINT SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* Premarket Approval (PMA) - July 30, 2025 *Application submitted to CMS:* August 4, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The SetPoint System 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 (DMARDs). *Breakthrough Device designation:* (March 15, 2024) The SetPoint System is indicated for the treatment of adult patients with moderate to severe RA who have had an inadequate response, loss of response or intolerance to one or more biological or targeted synthetic DMARDs.	No concerns.
§ 419.66(b)(3)	Device is integral to the service(s) furnished, used for one patient only, comes in contact with tissue, and is surgically implanted in the patient.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category codes C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), and C1826 (Generator, neurostimulator (implantable), do not describe the device.	No concerns.
Cost Criteria	The cost of the SetPoint System is $59,500.00. Per the applicant, the SetPoint System is packaged and sold as a single kit to hospitals, with the Implant, Charger and Docking Station included in a singular kit. As a result, no separate components or partial systems are sold to hospitals. For cost significance requirements: HCPCS code: 0908T APC code: 5465 CY 2026 device offset amount: $25,904.96 CY 2026 APC payment rate: $31,526.06 Requirement #1: ($59,500.00/ $31,526.06) x 100 = 188.73%. Requirement #2: ($59,500.00 / $25,904.96) x 100 = 229.69%. Requirement #3: (($59,500.00 - $25,904.96) / $31,526.06) x 100 = 106.56%.	No concerns.

The SetPoint System was preliminarily approved for device pass-through payment status effective January 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the SetPoint System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the SetPoint System meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the SetPoint System for device pass-through payment status for CY 2027.

(g) TIDAL™ Fusion Cage System (Ossera™ AFX)

restor3d submitted an application for a new device category for transitional pass-through payment status for the TIDAL™ Fusion Cage System for CY 2027. According to the applicant, the TIDAL™ Fusion Cage is a single, continuous, porous piece of titanium

alloy containing a circular window for an intramedullary nail used during salvage procedures to restore bone length due to bone void, absent bone or surgical resection. The TIDAL™ Fusion Cage System is composed of the TIDAL™ Fusion Cage and a Disposable Instrument Kit, which includes size trials, cannulated reamers, and inserters. The applicant stated that the TIDAL™ Fusion System is not for standalone use and is intended for use as an accessory to the DynaNail® TTC Fusion System and with an autograft and/or allogenic bone graft.

Table 36 provides an overview of the device category for transitional pass-through payment status application for TIDAL™ Fusion Cage System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250529B0B27.*

TABLE 36: TIDAL™ FUSION CAGE SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - March 24, 2025 *Application submitted to CMS:* May 29, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The TIDAL™ Fusion Cage System is intended for use as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The TIDAL™ Fusion Cage System is intended for use as an accessory to the DynaNail® TTC Fusion System. The TIDAL™ Fusion Cage System is not intended for standalone use. The TIDAL™ Fusion Cage System is intended for use with autograft and/or allogenic bone graft. *Breakthrough Device designation:* The restor3d Fusion Cage System is intended for tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft in procedures such as: post-traumatic and degenerative arthritis; post-traumatic or primary arthrosis involving both ankle and subtalar joints; revision after failed ankle arthrodesis with subtalar involvement; failed total ankle arthroplasty; non-union ankle arthrodesis; rheumatoid hindfoot; talectomy; avascular necrosis of the talus; neuroarthropathy; neuromuscular disease and severe deformity; osteoarthritis; Charcot foot; and previously infected arthrosis, second degree. The restor3d Fusion Cage System is intended to provide stabilization in long bones of skeletally mature patients, including tibia, femur and humerus, in the presence of critical sized bone defects in lieu of bulk allograft, bone transport or other treatment for segmental defects in procedures such as: stabilization of fractures of the diaphyseal or metaphyseal regions of long bones; malunions and nonunion; osteomyelitis; and periprosthetic fractures. Note: FDA granted Breakthrough Device designation to this device under the trade name restor3d Fusion Cage System, which the applicant later changed to TIDAL™ Fusion Cage System (Ossera™ AFX).	See following discussion.
§ 419.66(b)(3)	Device is integral to the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted into the ankle joint for permanent implantation.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1776 (Joint device (implantable)) and C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) do not describe the device.	See following discussion.
Cost Criteria	The TIDAL™ Fusion Cage System's total device cost is $32,995.00, consisting of a Fusion Cage ($27,995.00) and a Disposable Instrument Kit ($5,000.00). For cost significance requirements: HCPCS code: 27871 APC code: 5115 CY 2026 device offset amount: $5,973.37 CY 2026 APC payment rate: $13,116.76 Requirement #1: ($27,995 / $13,116.76) x 100 = 213.43%. Requirement #2: ($27,995 / $5,973.37) x 100 = 468.66%. Requirement #3: (($27,995 - $5,973.37) / $13,116.76) x 100 = 167.89%.	See following discussion.

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Regarding the Breakthrough Device designation, we note that restor3d submitted a new technology add-on payment application for FY 2026 for the TIDAL™ Fusion Cage under the alternative pathway, as discussed in the FY 2026 IPPS/LTCH PPS proposed and final rules (90 FR 18200 through 18202; 36817 through 36819). In the final rule, we stated that because the Disposable Instrument Kit was not included in the Breakthrough Device designation, only the TIDAL™ Fusion Cage was eligible for new technology add-on payments under the alternative pathway. Consistent with our decision regarding new technology add-on payment

eligibility, we will not consider the Disposable Instrument Kit for transitional pass-through payment status under the alternative pathway because it is not included in the Breakthrough Device designation. We will only be discussing the TIDAL™ Fusion Cage in the following paragraphs.

We are inviting public comment on whether the TIDAL™ Fusion Cage meets the newness criterion at § 419.66(b)(1).

We also are inviting public comment on whether the TIDAL™ Fusion Cage meets the eligibility criteria at § 419.66(b)(3) and (b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), the applicant stated that no existing (current or previous) device pass-through payment categories appropriately describe the TIDAL™ Fusion Cage. Per the applicant, the existing pass-through code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the TIDAL™ Fusion Cage because C1713 is typically used to represent fixation components, such as an intramedullary nail or other fixation screws, but does not represent the TIDAL™ Fusion Cage.

Based on the description the applicant provided, the TIDAL™ Fusion Cage is a porous cage used as part of a limb salvage arthrodesis construct to bridge bone loss or a critical bone defect in the ankle and restore length due to bone void, absent bone, or surgical resection and therefore, could be described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). Specifically, we believe that the pass-through payment category C1713 may appropriately describe the TIDAL™ Fusion Cage because C1713 is defined as implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact and may include orthopedic plates with accompanying washers or nuts as well as synthetic bone substitutes that may be used to fill bony voids or gaps.[33] In this context, we believe that the TIDAL™ Fusion Cage may be appropriately described by C1713.

We are inviting public comment on whether the TIDAL™ Fusion Cage meets the device category eligibility criterion at § 419.66(c)(1).

We are also inviting public comment on whether the TIDAL™ Fusion Cage meets the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the TIDAL™ Fusion Cage meets the new device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for the TIDAL™ Fusion Cage for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the TIDAL™ Fusion Cage for CY 2027.

[33] Centers for Medicare & Medicaid Services. (2024). *Medicare Claims Processing Manual* (CMS Pub. 100–04), Chapter 4: Part B Hospital (including inpatient hospital part B and OPPS). U.S. Department of Health and Human Services. *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf.*

(h) TOPS™ System

Premia Spine, Inc. submitted an application for a new device category for transitional pass-through payment status for the TOPS™ System for CY 2027. According to the applicant, the TOPS™ System is a motion preserving device comprised of a titanium construct with an interlocking polycarbonate urethane (PcU) articulating core that is inserted into the lumbar vertebral joint after open posterior decompression and anchored using pedicle screws, preserving normal spinal motion and providing stabilization of the lumbar intervertebral segment. According to the applicant, the TOPS™ System replaces anatomical structures, such as the lamina and facet joints removed during spinal decompression treatment to alleviate pain, while preserving normal spinal motion and stabilizing the lumbar intervertebral segment. Per the applicant, unlike lumbar fusion, the TOPS™ System preserves normal biomechanical motion allowing relative motion in axial rotation, lateral bending, flexion, and extension while blocking sagittal translation, and stabilizing the spine after a decompression.

Table 37 provides an overview of the transitional device pass-through payment status application for the TOPS™ System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2602261DX3J.*

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TABLE 37: TOPS™ APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* Premarket Approval (PMA) - June 15, 2023 *Application submitted to CMS:* February 27, 2026	No concerns.
Breakthrough Device Designation	*FDA Indication:* The TOPS™ System is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The TOPS™ System is intended to stabilize the spine following a lumbar decompression without rigid fixation. The TOPS™ System is indicated for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5. The date of the TPT application is within three years of FDA approval of the TOPS™ System *Breakthrough Device designation:* (October 26, 2020) The proposed indications for use includes patients between 35 and 80 years of age suffering from neurogenic claudication resulting from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum or scaring facet joint capsule at one level from L2 to L5.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically implanted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)), C1741 (Anchor/screw for bone fixation, absorbable, metallic (implantable)), C1821 (Interspinous process distraction device (implantable)), C1831 (Interbody cage, anterior, lateral or posterior, personalized (implantable)), C1737 (Joint fusion and fixation device(s), sacroiliac and pelvis, all system components (implantable)), and C1776 (Joint device (implantable)) do not encompass the device.	No concerns.
Cost Criteria	The cost of the TOPS™ System is $16,500.00. Per the applicant, to complete the implant procedure of the TOPS™ System, the following components are required: one TOPS™ Implant ($13,900.00), four TOPS™ Pedicle Screws ($600.00 each), and four TOPS™ Set Screws ($50.00 each). No partial systems are created by components. For cost significance requirements: HCPCS code: 0202T APC code: 5115 CY 2026 device offset amount: $8,065.50 CY 2026 APC payment rate: $13,116.76 Requirement #1: ($16,500.00 / $13,116.76) x 100 = 125.79%. Requirement #2: ($16,500.00 / $8,065.50) x 100 = 204.58%. Requirement #3: (($16,500.00- $8,065.50) / $13,116.76) x 100 = 64.30%.	No concerns.

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The TOPS™ System was preliminarily approved for device pass-through payment status effective July 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the TOPS™ System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the TOPS™ System meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the TOPS™ System for device pass-through payment status for CY 2027.

(i) TOUCH® CMC 1 Prosthesis

Medartis submitted an application for a new device category for transitional pass-through payment status for the TOUCH® CMC 1 Prosthesis for CY 2027. According to the applicant, the TOUCH® CMC 1 Prosthesis is a cementless, ball-and-socket dual-mobility, total first carpometacarpal (CMC 1) joint prosthesis composed of a metacarpal implant (stem), trapezial implant (cup), and junction implant (neck), and has multiple sizes and

variants to fit patient anatomy. According to the applicant, the TOUCH® CMC 1 Prosthesis is the first total joint prosthesis for the CMC 1 joint and enables functional improvement, pain reduction, and improvements in patient quality of life.

Table 38 provides an overview of the transitional device pass-through payment status application for the TOUCH® CMC 1 Prosthesis and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250829G4VEC.*

TABLE 38: TOUCH® CMC 1 PROSTHESIS APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* Premarket Approval (PMA) - July 10, 2025 *Application submitted to CMS:* August 29, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The TOUCH® CMC 1 Prosthesis is indicated for 1st carpometacarpal (CMC) primary total joint replacement (arthroplasty) in patients with symptomatic Eaton-Littler stage II or III osteoarthritis (OA). *Breakthrough Device designation:* The TOUCH® CMC 1 Prosthesis is indicated for replacement of the trapeziometacarpal joint due to rheumatoid arthritis, traumatic arthritis, osteoarthritis, and post-fracture deformation or bone loss. The TOUCH® CMC 1 Prosthesis received FDA Breakthrough Device Designation under the name TOUCH® Dual Mobility Trapeziometacarpal Prosthesis on November 10, 2021.	No concerns.
§ 419.66(b)(3)	Device is integral to the service furnished (1003T), used for one patient only, comes in contact with tissue, and is surgically implanted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category code C1776 Joint Device (implantable) does not encompass the device.	No concerns.
Cost Criteria	The cost of the TOUCH® CMC 1 Prosthesis is $8,985.00. Per the applicant, the TOUCH® CMC 1 Prosthesis includes three one-time-use components: Cementless TOUCH® Cup ($3,095.00), TOUCH® Neck + HR Liner ($2,995.00), and Cementless TOUCH® Stem ($2,895.00). The applicant stated that there are no partial systems created, and all three components are essential to creating a total joint arthroplasty prosthesis. For cost significance requirements: HCPCS code: 1003T APC code: 5115 CY 2026 device offset amount: $5,895.98 CY 2026 APC payment rate: $13,116.76 Requirement #1: ($8,985.00 / $13,116.76) x 100 = 68.50%. Requirement #2: ($8,985.00 / $5,895.98) x 100 = 152.39%. Requirement #3: (($8,985.00 - $5,895.98) / $13,116.76) x 100 = 23.55%.	No concerns.

The TOUCH® CMC 1 Prosthesis was preliminarily approved for device pass-through payment status effective January 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the TOUCH® CMC 1 Prosthesis under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the TOUCH® CMC 1 Prosthesis meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the TOUCH® CMC 1 Prosthesis for device pass-through payment status for CY 2027.

(j) WiSE® (Wireless Stimulation of the Endocardium Technology) CRT System

EBR Systems, Inc. submitted an application for a new device category for transitional pass-through payment status for the WiSE® CRT System for CY 2027. According to the applicant, the WiSE® CRT System is an implantable, cardiac device capable of pacing the heart without a lead. It includes a subcutaneously implanted transmitter that generates ultrasonic pulses that

travel to a receiver implanted in the heart. The receiver, also known as the electrode, converts ultrasonic waves into electrical energy to stimulate cardiac tissue. The WiSE® CRT System uses leadless technology to stimulate the endocardial surface of the LV. Working in conjunction with a standard commercially available pacemaker (with or without leads) or defibrillator already implanted in the patient, the WiSE® CRT System replaces the pacing function of a coronary sinus (CS) lead to achieve cardiac resynchronization therapy (CRT).

Table 39 provides an overview of the transitional device pass-through payment status application for the WiSE® CRT System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250429663YG.*

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TABLE 39: WISE® CRT SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* Premarket Approval - April 11, 2025 *Application submitted to CMS:* April 29, 2025	No concerns.
Breakthrough Device Designation	*FDA Indication:* The WiSE® CRT System is indicated for adult patients who are at least 22 years of age, are indicated for cardiac resynchronization therapy (CRT), have an existing or are eligible for an implanted right ventricular pacing system, and are in one of the following two categories: 1) Patients in whom previous coronary sinus (CS) lead implantation was unsuccessful, or where an implanted lead has been turned off, referred to as "previously untreatable" 2)Patients with previously implanted pacemakers or Implantable Cardioverter-Defibrillators (ICDs) in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation, referred to as "high risk upgrades". *Breakthrough Device designation:* (July 18, 2019) The WiSE® CRT System is indicated for adult patients at least 22 years of age who are indicated for cardiac resynchronization therapy (CRT), have an existing implanted right ventricular pacing system, and are either patients in whom previous coronary sinus lead implantation was unsuccessful or an implanted lead has been turned off ("previously untreatable"), or in patients with previously implanted pacemakers or ICDs in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation ("high risk upgrades").	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category codes C1605 (Pacemaker, leadless, dual chamber (right atrial, right ventricular implantable components), C2621 (Pacemaker, other than single or dual chamber (implantable)), C2619 (Pacemaker, dual chamber, non-rate responsive (implantable)), C1785 (Pacemaker, dual chamber, rate responsive (implantable)), C1786 (Pacemaker, single chamber, rate-responsive (implantable)), and C2620 (Pacemaker, single chamber, non-rate responsive (implantable)) do not describe the device.	No concerns.
Cost Criteria	The cost of WiSE® CRT System is $63,300.00. Per the applicant, the WiSE® CRT System consists of single-use components electrode and catheter ($21,970.00), delivery sheath ($2,590.00), transmitter ($22,870.00) and battery ($15,870.00) that are eligible for device pass-through payment, and a reusable controller ($6,000.00). For cost significance requirements:[34] HCPCS code: 0515T APC code: 5231 CY 2025 device offset amount: $15,487.87 CY 2025 APC payment rate: $22,446.19 Requirement #1: ($63,300.00 / $22,446.19) x 100 = 282.01%. Requirement #2: ($63,300.00 / $15,487.87) x 100 = 408.71%. Requirement #3: (($63,300.00 - $15,487.87) / $22,446.19) x 100 = 213.01%.	No concerns.

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The WiSE® CRT System was preliminarily approved for device pass-through payment status effective October 1, 2025. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the WiSE® CRT System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

[34] We note that the applicant selected the APC level device offset amount of $15,312.79 for APC 5231 found in CY 2025 NFRM APC Offset File. Beginning in CY 2017, we calculate the device offset amount at the HCPCS code level instead of the APC level (81 FR 79657). We note the HCPCS code level device offset amounts for the HCPCS codes provided by the applicant are available in the Addendum P to the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912). For our calculation, we selected the HCPCS level device offset amount of $15,487.87 related to HCPCS 0515T in APC 5231 found in the Addendum P. Based on our initial assessment for this proposed rule, using the device offset amount of $15,487.87

After review of the information provided by the applicant, we agree that the WiSE® CRT System meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the WiSE® CRT System for device pass-through payment status for CY 2027.

(2) Traditional Device Pass-Through Applications

(a) EndoForce™ Connector for Endovascular Venous Anastomosis

Phraxis Inc. submitted an application for a new device category for transitional pass-through payment status for the EndoForce™ Connector for Endovascular Venous Anastomosis (the EndoForce™ System) for CY 2027. According to the applicant, the EndoForce™ System provides an endovascular method for attachment of a non-autogenous arteriovenous graft (AVG) to a vein in the upper arm in patients with end stage renal disease (ESRD) requiring hemodialysis. Per the applicant, the EndoForce™ System is provided as a sterile, single-use EndoForce™ Connector Delivery System with a pre-mounted EndoForce™ Connector that is attached endovascularly at the venous anastomosis, in conjunction with a standard 6mm expanded polytetrafluoroethylene (ePTFE) vascular access graft, to establish an end-to-end endovascular anastomotic conduit designed to help absorb the shear forces of blood flow at the AVG-vein junction and to provide a physical barrier to the ingress of neointimal hyperplasia.

Table 40 provides an overview of the transitional pass-through payment status application for the EndoForce™ System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP260228AHPFT*.

would result in WiSE® CRT System meeting the cost significance requirement.

TABLE 40: ENDOFORCE™ SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization*: PMA approval - May 15, 2025. *Application submitted to CMS*: February 28, 2026.	No concerns.
FDA Indication	The EndoForce™ System is indicated to provide an endovascular method for attachment of an AVG to a vein in the upper arm in patients with ESRD requiring hemodialysis. The EndoForce™ Connector is used together with conventional suturing of the graft to the artery during the implantation procedure. The graft is then used for vascular access during hemodialysis.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is surgically inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1768 (Graft, vascular), C1874 (Stent, coated/covered, with delivery system), C1875 (Stent, coated/covered, without delivery system), C1876 (Stent, non-coated/non-covered, with delivery system), C1877 (Stent, non-coated/non-covered, without delivery system), and C8000 (Support device, extravascular, for arteriovenous fistula (implantable)) do not describe the device.	No concern.
Cost Criteria	The cost of the EndoForce™ System is $5,000.00. For cost significance requirements: HCPCS code: 36830 APC code: 5184 CY 2026 device offset amount: $1,474.69 CY 2026 APC payment rate: $5,685.01 Requirement #1: ($5,000.00 / $5,685.01) x 100 = 87.95%. Requirement #2: ($5,000.00 / $1,474.69) x 100 = 339.05%. Requirement #3: (($5,000.00 - $1,474.69) / $5,685.01) x 100 = 62.01%.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: Improved Patency, Reduced Intervention Burden, and Reduced AVG Abandonment at 6 months. Claim #2: Improved Patency and Reduced AVG Abandonment. Claim #3: Sustained Patency and Fewer Interventions to Maintain Patency. Claim #4: Improved Cumulative (Secondary Patency) Compared to Sutured AVGs. Claim #5: Improved Cumulative (Secondary Patency) Compared to Mature AV Fistulas. Claim #6: Improved Cumulative Patency Compared to WaveLinQ™. Claim #7: Improved Cumulative Patency Compared to Ellipsys™. Claim #8: Reduced Interventions Compared to Traditional AVGs. Applicant provided one published study assessing the technology, two unpublished studies assessing the technology, and six background documents.	See following discussion.

We are inviting public comments on whether the EndoForce™ System meets the newness criterion at § 419.66(b)(1), the eligibility criteria at § 419.66(b)(3) and (b)(4), and the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we have the following concerns regarding whether the EndoForce™ System meets the substantial clinical improvement criterion.

In support of claims one through four, eight, and nine, the applicant submitted a single published study evaluating the EndoForce™ System: Burgess et al. (2024), two un-published studies assessing the EndoForce™ System: Kramer et al. (n.d.) and Astor et al. (n.d.), and three background studies: Halbert et al. (2020), Harms et al. (2016), and Woodside et al. (2021) which did not assess the nominated device. In support of claims five through seven the applicant submitted three background articles (Pisoni et al. (2021); Berland et al. (2019); Hull et al. (2018)) which did not assess the nominated device.[35] [36] [37]

[35] Pisoni, R. L., Zepel, L., Zhao, J., Burke, S., Lok, C. E., Woodside, K. J., Wasse, H., Kawanishi, H., Schaubel, D. E., Zee, J., & Robinson, B. M. (2021). International Comparisons of Native Arteriovenous Fistula Patency and Time to Becoming Catheter-Free: Findings From the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American journal*

The Burgess et al. (2024) study is a single-arm, non-randomized study that analyzed the use of the EndoForce™ System in 158 patients aged 18 and older diagnosed with ESRD scheduled to have an AVG for hemodialysis placed in their upper arm in 10 U.S. institutions between 2018 and 2021 after a 6-month follow-up period.[38] We have several concerns with this study.

First, we are concerned that the study does not provide a comparison to a control group, such as patients treated with standard graft-to-vein sutured anastomosis. Without a comparison to currently available treatments, particularly in the clinical setting where it is most likely to be used, we are unable to assess whether the EndoForce™ System demonstrates substantial clinical improvement over currently available treatments. To demonstrate substantial clinical improvement, we consider supporting evidence, preferably published peer-reviewed clinical trials, that show improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to other currently available treatments.

Second, we are concerned that the smaller patient population and study design of Burgess et al. (2024), and the lack of stratification by key clinical factors known to affect AVG outcomes, may limit both the reliability of the cumulative patency findings and the generalizability of results to the Medicare population. Stratification factors, such as coronary artery disease, hypertension status, and ipsilateral access placement, which have all been shown to be associated with thrombosis, need for intervention, and cumulative patency would be helpful to assess the outcomes.

In addition, it is unclear to what extent any improvement in cumulative patency is due to use of the EndoForce™ Connector versus the less invasive endovascular procedure used for implantation. We would welcome additional information on differentiating how the EndoForce™ System's connection to AVG versus the less invasive nature of the endovascular procedure leads to improvements in cumulative patency.

Furthermore, we note that, in Burgess et al. (2024), the authors compared results to three background studies, Halbert et al. (2020) (submitted in support of claim 4), Harms et al. (2016) (submitted in support of claim 8), and Woodside et al. (2021) (submitted in support of claim 8), none of which directly address the EndoForce™ System.[39] [40] [41] We question the appropriateness of comparing cumulative patency, intervention rates, and AVG abandonment in Burgess et al. (2024) to outcomes reported in the three background studies, as observed differences may be influenced by variations in study design, study location, patient population and characteristics, and study period. Specifically, Burgess et al. (2024) reports a 6-month cumulative patency of 92 percent in its patient population and compares it to the 80 percent rate reported in Halbert et al. (2020). However, Halbert et al. (2020) is a meta-analysis of 32 studies conducted across 14 countries between 2007 and 2019, representing 3,381 AVGs placed in patients with chronic kidney disease or ESRD undergoing or preparing for hemodialysis using ePTFE grafts. In contrast, Burgess et al. (2024) analyzed ESRD patients between 2018 and 2021. Thus, we question whether the results in Halbert et al. (2020), which included studies dating back more than a decade, reflect current operative techniques and perioperative care in the U.S. and therefore whether they are an appropriate comparator to Burgess et al. (2024). Similarly, Harms et al. (2016) is a retrospective study of 599 patients treated between January 2006 and December 2011, and Woodside et al. (2021) is an observational cohort study of 73,027 patients using data from July 2012 to December 2014. These studies reflect earlier clinical practices and patient populations that differ from those in Burgess et al. (2024), which evaluated patients between 2018 and 2021. Burgess et al. (2024) compared its reported intervention rate of 1.22 per patient-year to higher rates reported in Harms et al. (2016) and Woodside et al. (2021), 1.58 and 1.87 respectively; however, these comparisons may not be appropriate given the significant differences in study design, time periods and patient populations. These earlier studies do not adequately account for changes in clinical practice over time and any observed differences in outcomes are likely confounded by these factors rather than attributable to the technology itself. As such, these studies may not provide a valid basis for comparison to Burgess et al. (2024).

Moreover, we note patient populations varied across studies, and it is unclear how these differences may have affected intervention rates per patient-year. For example, Burgess et al. (2024) included patients with two or fewer previous vascular accesses in the treatment arm, while Woodside et al. (2021) included patients undergoing a first-time AVG placement between dialysis initiation and 1 year. We note that patients who have had previous hemodialysis access points experience damage to the blood vessels regardless of whether the access point is a central venous catheter, AVG, or AVF.[42] [43] Further, having prior vascular access points in the ipsilateral arm has been shown to decrease cumulative patency in Harms et al. (2016). We welcome additional studies that control for patients with comparable vascular access placement histories, to more accurately quantify the contributions of the EndoForce™ System to improvements in interventions per patient-year.

Finally, we are concerned that differences in vascular location for

of kidney diseases: the official journal of the National Kidney Foundation, 77(2), 245–254. *https://doi.org/10.1053/j.ajkd.2020.06.020.*

[36] Berland, T. L., Clement, J., Griffin, J., Westin, G. G., & Ebner, A. (2019). Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4 Fr Device: Clinical Experience from the EASE Study. *Annals of vascular surgery, 60,* 182–192. *https://doi.org/10.1016/j.avsg.2019.02.023.*

[37] Hull, J. E., Jennings, W. C., Cooper, R. I., Waheed, U., Schaefer, M. E., & Narayan, R. (2018). The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *Journal of vascular and interventional radiology: JVIR,* 29(2), 149–158.e5. *https://doi.org/10.1016/j.jvir.2017.10.015.*

[38] Burgess, J. S., Beaver, J. D., London, M., Rohan, V., Orland, P., Yevzlin, A., Setum, C., Ross, J., & InterGraft Study Investigators. (2024). Prospective multicenter study of a novel endovascular venous anastomotic procedure and device for implantation of an arteriovenous graft for hemodialysis. *The Journal of Vascular Access, 25*(4), 1244–1251. *https://doi.org/10.1177/11297298231159691.*

[39] Halbert, R. J., Nicholson, G., Nordyke, R. J., Pilgrim, A., & Niklason, L. (2020). Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients: Systematic Literature Review and Meta-Analysis. *Kidney360, 1*(12), 1437–1446. *https://doi.org/10.34067/kid.0003502020.*

[40] Harms, J. C., Rangarajan, S., Young, C. J., Barker-Finkel, J., & Allon, M. (2016). Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use. *Journal of Vascular Surgery, 64*(1), 155–162. *https://doi.org/10.1016/j.jvs.2016.02.033.*

[41] Woodside, K. J., Repeck, K. J., Mukhopadhyay, P., Schaubel, D. E., Shahinian, V. B., Saran, R., & Pisoni, R. L. (2021). Arteriovenous Vascular Access-Related Procedural Burden Among Incident Hemodialysis Patients in the United States. *American Journal of Kidney Diseases, 78*(3), 369–379.e1. *https://doi.org/10.1053/j.ajkd.2021.01.019.*

[42] Harms, J. C., Rangarajan, S., Young, C. J., Barker-Finkel, J., & Allon, M. (2016). Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use. *Journal of Vascular Surgery, 64*(1), 155–162. *https://doi.org/10.1016/j.jvs.2016.02.033.*

[43] Lok, C. E., Huber, T. S., Orchanian-Cheff, A., & Rajan, D. K. (2024). Arteriovenous access for hemodialysis: A review. *Journal of American Medical Association,* 331(15), 1307–1317. *https://doi.org/10.1001/jama.2024.0535.*

patients in the Burgess et al. (2024) compared to patients in the background studies may influence outcomes and adversely impact comparability of results. Specifically, while Burgess et al. (2024) evaluated patients with upper arm AVGs consistent with the EndoForce™ System's FDA indication, this varied across the comparator studies: Halbert et al. (2020) excluded studies that exclusively assessed lower extremity AVGs, Harms et al. (2016) included patients who had AVGs in the chest and thigh in addition to the upper extremity, and Woodside et al. (2021) did not specify the anatomical location of AVGs. It is unclear whether some of the studies included patient populations with upper extremity, lower extremity, and chest AVGs. As discussed in greater detail later in this section for the second claim, it is unclear whether upper extremity and upper arm are used interchangeably. We question whether vascular access location influences clinical outcomes, and as such, the results in these background studies may be confounded by inclusion of patients with additional graft locations that could adversely impact the comparability of the results to Burgess et al. (2024).

With regard to the second claim that the EndoForce™ System improves patency and reduces AVG abandonment, the applicant submitted one unpublished analysis (Astor et al. (n.d.)) that compared the primary patency (defined as the time interval from initial implantation until first intervention) and cumulative patency (defined as the time interval between implantation of the graft to abandonment) results from Burgess et al. (2024) to pooled results from a meta-analysis of 34 studies of AVGs implanted using traditional surgical techniques.[44] We are concerned that Astor et al. (n.d.) may not demonstrate that the EndoForce™ System substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. Astor et al. (n.d.) reported a high degree of variability among the comparator studies included in the meta-analysis (primary patency I^2=99.44; cumulative patency I^2=99.36), many of which showed similar or higher primary patency (60.21 percent; 95 percent confidence interval (CI): 50.84, 69.59) and cumulative patency (92.08 percent; 95 percent CI: 86.98, 97.18) compared to results from Burgess et al. (2024). We note that 19 of the 31 studies that provided data on cumulative patency in Astor et al. (n.d.) did not specifically report 6-month patency outcomes in tables or text the studies only provided data in survival curves from which the authors of Astor et al. (n.d.) derived 6-month patency measurements. The estimated 6-month cumulative patency including all 31 studies was 83.23 percent (95 percent CI: 80.18, 86.28), whereas the 6-month cumulative patency estimated from the 12 studies reporting numerical values was 86 percent (95 percent CI: 81.78, 90.22). Astor et al. (n.d.) did not state whether the difference between the 6-month cumulative patency rates of 92 percent in Burgess et al. (2024) and 86 percent was statistically significant. However, we note the lower 95 percent CI bound reported in Burgess et al. (2024) was 86.98 percent, lower than the upper 95 percent CI bound of 90.22 percent for the 12 studies in Astor et al. (n.d.) providing numerical data. We also note that Astor et al. (n.d.) states that the primary patency for the EndoForce™ System is similar to pooled results from comparator studies (60.21 percent vs 60.35 percent; p=0.75). Additionally, we note that the 20 percent AVG abandonment rate used as a baseline by Astor et al. (n.d.) which they report was reduced to 8 percent, comes from a single meta-analysis (Halbert) based on 32 studies from 14 countries conducted between 2007 and 2019. We question whether this is an appropriate comparator to the 158 patients treated between 2018 and 2021 in 10 U.S. institutions reported in Burgess et al. (2024).

We also note that the criteria for comparator studies included in the meta-analysis in Astor et al. (n.d.) excluded those studies which only assessed lower extremity or chest AVGs. However, it is unclear whether some of the studies included patient populations with upper extremity AVGs as well as lower extremity and chest AVGs. As previously discussed, vascular access location may influence outcomes, therefore, the results in these background studies may be confounded by inclusion of patients with additional graft locations that could adversely impact the comparability of the results to Burgess et al. (2024). Additionally, because of the EndoForce™ System's FDA indication for use in the upper arm, we question whether the comparison is appropriate. Further, we note it is unclear in the application whether the upper arm means the entire upper extremity, including the forearm (distal to the elbow) or only a portion of the arm (proximal to the elbow). We are interested in additional information clarifying the meaning of upper arm to help us evaluate the evidence provided in support of substantial clinical improvement and determine if it is applicable.

With regard to the third claim that the EndoForce™ System sustains patency and requires fewer interventions to maintain patency, the applicant submitted one unpublished, extended follow-up study (Kramer et al. (n.d.)) of 37 patients from Burgess et al. (2024), that evaluates the number of interventions performed to achieve cumulative patency for an additional 6 months beyond the most recent intervention.[45] Similar to our concerns regarding Burgess et al. (2024), we are concerned that Kramer et al. (n.d.) does not provide a control group for comparison. We note that the authors in Kramer et al. (n.d.) stated that, since both the EndoForce™ System's pivotal trial (Burgess et al. (2024)) as well as this extended follow-up study do not directly compare outcomes to sutured AVGs, a meta-analytic approach to compare endovascular anastomosis of an AVG with a traditional sutured anastomosis may be warranted. We would welcome additional information directly comparing endovascular anastomosis of an AVG with a traditional sutured anastomosis.

Like Burgess et al. (2024), the authors of Kramer et al. (n.d.) compared results to two background studies, Harms et al. (2016) and Woodside et al. (2021), neither of which directly address the EndoForce™ System. As mentioned previously, we question whether the comparison of rates of interventions per patient-year in Kramer et al. (n.d.) to Harms et al. (2016) and Woodside et al. (2021) are appropriate and reflect true improvements or are attributable to differences in study design, patient population, and study period. Kramer et al. (n.d.) reported a rate of 1.32 interventions per patient-year in its patient population using the nominated technology and compared it to rates of 1.58 and 1.87 reported in Harms et al. (2016) and Woodside et al. (2021). However, as previously noted in our discussion of the first claim that the EndoForce™ System improves patency, reduces intervention burden, and reduces AVG abandonment at 6 months, due to the differences in study periods between Kramer et al. (n.d.) and Harms

[44] Astor, B.C., Moorthi, K., Grant, L., Litchfield, T. (Pre-publication). Endovascular AVG venous anastomosis improves cumulative patency compared to traditional sutured anastomosis: a meta-analysis.

[45] Kramer, A., Moorthi, K., Grant, L., Litchfield, T. (Pre-publication). Extended Follow-Up of an Endovascular Venous Anastomotic Connector for Arteriovenous Graft Creation in Hemodialysis: A Multicenter Study.

et al. (2016) and Woodside et al. (2021), we question whether the results in the comparator studies, some of which are over a decade old, reflect current operative techniques and latest perioperative care in the U.S. Also, as previously noted in our discussion of the first claim, the extent of variance in vascular access locations of the patient populations assessed in these three studies is unclear. As such, we are concerned that the results in these background studies may be confounded by inclusion of patients with additional graft locations which could adversely impact the comparability of the results to Kramer et al. (n.d.).

We are also concerned about whether the patient population in Kramer et al. (n.d.), which included 29 active patients at the end of the study period from the 37 patients initially assessed, is powered sufficiently to assess statistical significance, especially compared to Burgess et al. (2024), which included 134 active patients at the end of the study period from the 158 patients initially assessed. We note that when a study is not adequately powered for the statistical analysis, the statistics may appear artificially inflated and do not reflect confounding effects. Further, we are concerned that the cohort in Kramer et al. (n.d.) was selected and analyzed post-hoc, rather than identified as a variable of interest at the initiation of Burgess et al. (2024), and question whether quality of the study was diminished due to selection bias.

Additionally, we question whether Kramer et al. (n.d.) conclusively demonstrates that the EndoForce™ System provides a substantial clinical improvement compared to other available treatments. Kramer et al. (n.d.) estimated a cumulative patency of 78.4 percent at 180 days into the extended follow-up period (12 months from AVG implant at the start of Burgess et al. (2024)). In comparison, Halbert et al. (2020) reported a 12-month cumulative patency of 70 percent (95 percent CI: 64, 75). We also note the high degree of variability (I^2=91) among the comparator studies in Halbert et al. (2020), many of which showed similar or higher cumulative patency compared to Kramer et al. (n.d.). Therefore, we are unable to conclusively attribute the difference in outcomes to the nominated device.

Lastly, we question the appropriateness of comparing measures of cumulative patency that are not equally defined. Kramer et al. (n.d.) compared cumulative patency between participants with and without graft interventions within the 6-month study period discussed in Burgess et al. (2024) and stated that the cumulative patency at 6 months was nearly identical (91.79 percent versus 91.80 percent, respectively). In Kramer et al. (n.d.), for patients without an intervention, time to loss of patency was measured from the date of implant, while for patients with interventions, time to loss of patency was measured from the date of first intervention. We question the appropriateness of comparing cumulative patency between AVGs used at first hemodialysis without intervention and those that required intervention prior to first hemodialysis use. As Harms et al. (2016) notes, intervention prior to first hemodialysis use is associated with a shortened cumulative patency. As such, we question if making such comparisons could be potentially misleading.

In support of claims five through seven, that the EndoForce™ System improves cumulative (secondary) patency compared to mature AV fistulas (AVFs), and devices used for AVF creation, including WaveLinQ™, and Ellipsys™, the applicant submitted three background articles (Pisoni et al. (2021); Berland et al. (2019); Hull et al. (2018)) which did not assess the nominated device.[46] [47] [48] The applicant stated that improvement in AVG patency is comparable to the 6-month cumulative patency associated with mature AVFs (71 to 93 percent) (Liu, P. et al. (2023)). However, we note that the EndoForce™ System is indicated for attachment of an AVG to a vein, not for the creation of an AVF. An AVF involves a direct anastomosis between an artery and a vein, whereas an AVG uses a graft as a conduit between the artery and the vein. Therefore, we question whether it is clinically appropriate to compare the EndoForce™ System, a device used for AVG attachment, to mature AVFs and devices used for AVF creation, including WaveLinQ™ and Ellipsys™. Given these fundamental differences in mechanism and clinical use, we question whether these claims demonstrate a substantial clinical improvement over existing technologies.

We are inviting public comment on whether the EndoForce™ System meets the device category criterion at § 419.66(c)(2) and the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the EndoForce™ System meets the new device category eligibility criteria, and therefore, we propose to deny the transitional pass-through payment status for the EndoForce™ System for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the EndoForce™ System for CY 2027.

(b) LINK™ External Fixator

Metric Medical Devices, Inc. submitted an application for a new device category for transitional pass-through payment status for the LINK™ External Fixator for CY 2027. According to the applicant, the LINK™ External Fixator is a dynamic percutaneous bone external fixator that provides continuous compression during the healing of bony fractures, fusions, and osteotomies. The applicant stated that the LINK™ External Fixator is composed of the (1) LINK™, a stainless steel box-shaped spring that applies forces to wires or pins inserted in the bone to either actively pull together and compress or distract the bones; (2) LINK™ Cover, a silicone cap that covers the bone pins or wire; and (3) LINK™ Bone Pins, which are inserted in a patient's bones and to which the LINKÔ attaches.

Table 41 provides an overview of the transitional pass-through payment status application for the LINK™ External Fixator and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250902M814F.*

[46] Pisoni, R. L., Zepel, L., Zhao, J., Burke, S., Lok, C. E., Woodside, K. J., Wasse, H., Kawanishi, H., Schaubel, D. E., Zee, J., & Robinson, B. M. (2021). International Comparisons of Native Arteriovenous Fistula Patency and Time to Becoming Catheter-Free: Findings From the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American journal of kidney diseases: the official journal of the National Kidney Foundation, 77*(2), 245–254. *https://doi.org/10.1053/j.ajkd.2020.06.020.*

[47] Berland, T. L., Clement, J., Griffin, J., Westin, G. G., & Ebner, A. (2019). Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4 Fr Device: Clinical Experience from the EASE Study. *Annals of vascular surgery, 60,* 182–192. *https://doi.org/10.1016/j.avsg.2019.02.023.*

[48] Hull, J. E., Jennings, W. C., Cooper, R. I., Waheed, U., Schaefer, M. E., & Narayan, R. (2018). The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *Journal of vascular and interventional radiology: JVIR,* 29(2), 149–158.e5. *https://doi.org/10.1016/j.jvir.2017.10.015.*

TABLE 41: LINK™ EXTERNAL FIXATOR APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - May 29, 2024 *Application submitted to CMS*: September 2, 2025	No concerns.
FDA Indication	Indications for use: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude LINK™ bone pin placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.	No concerns.
§ 419.66(b)(3)	Device is integral to the service(s) furnished, used for one patient only, comes in contact with human tissue, and is surgically inserted/implanted/applied in or on a wound or other skin lesion.	See following discussion.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not describe the device.	See following discussion.
Cost Criteria	The cost of the LINK™ External Fixator is $4,800. This cost includes the 4-pin LINKÔ and the corresponding LINKÔ Cover ($4,500) as well as two LINKÔ Bone Pin packages (2 pins in each package) ($300).[49] For cost significance requirements:[50] HCPCS code: 28899 APC code: 5111 CY 2025 device offset amount: $50.18 CY 2025 APC payment rate: $239.88 Requirement #1: ($4,800 / $239.88) x 100 = 2,001.00%.	No concerns.
	Requirement #2: ($4,800 / $50.18) x 100 = 9,565.56%. Requirement #3: (($4,800 - $50.18) / $239.88) x 100 = 1,980.08%.	
Substantial Clinical Improvement Criterion	Claim #1: The LINK™ External Fixator offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, such as those patients with infected sites, metal allergies, anesthesia sensitivity, skin pathology, or other co-morbidities such as diabetes, neuropathy or immunocompromised patients, due to the minimally invasive nature of the bone fixation the LINK™ External Fixator provides. Claim #2: The LINK™ External Fixator significantly improves clinical outcomes for a patient population as compared to currently available treatments because of its ability to percutaneously fixate fractures, osteotomies, or arthrodesis, thus protecting the soft tissue envelope, vascular, and neural structures, which historically result in a more robust healing response and a shorter time to function. Two documents describing the nominated technology and its fundamental principles were provided. No published or unpublished studies assessing the technology were provided.	See following discussion.

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We are inviting public comment on whether the LINK™ External Fixator meets the newness criterion at § 419.66(b)(1).

[49] Per the applicant, the LINKT is the shape changing force creating bridging element between bone pin implants with the fracture or site of fusion between the pins. The cost and components listed in the table are for a 4-pin LINKT External Fixator. According to the applicant, a 2-pin LINKT External Fixator is available and would cost $3,650 for the 2-pin LINKT and LINKT Cover ($3,500) as well as one LINKT Bone Pin package (2 pins in each package) ($150). Each LINKT package includes a cover to protect it from the environment. Additional LINKT Covers can be purchased in a separate package if a replacement cover is needed ($300 for a 2-pin cover or $350 for a 4-pin cover). Per the applicant, all components (LINKT, LINKT Bone Pins, and LINKT Cover) are required, and there are no partial systems. The applicant stated that multiple LINKT units may be used for higher level musculoskeletal procedures, such as five LINKT units for a Lisfranc dislocation, complex fractures, or Charcot foot fixation.

Regarding the eligibility criterion at § 419.66(b)(3), we are concerned that the LINK™ External Fixator components may not be integral to the service furnished, come in contact with human tissue, or be surgically inserted or implanted.

With respect to whether the LINK™ Bone Pins and LINK™ Cover are integral to the service furnished, based on the information provided by the applicant, we question whether the components are necessary to furnish or deliver the primary procedure with which it is used. We note that, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005), we stated that we have interpreted the term ''integral'' to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. According to the applicant, the LINK™ uses a single- use external fixator consisting of a stainless-steel bridge spring formed into a box shape, with holes that are held in alignment by surgical needle drivers during pin placement. When released, the bridge shortens to apply forces and the side elements swing outward to create moments on bone fixation pins or wires embedded in bone, pulling together and compressing or distracting bony structures. While the LINK™ External Fixator may include LINK™ Bone Pins, per the applicant, other commercially available bone pins, k-wires, or Steinmann pins (hereinafter referred to collectively as ''bone fixation pins or wires'') may be compatible with the LINK™ External Fixator, and we therefore question whether the LINK™ Bone Pins are integral to the service furnished as they may be replaced with other commercially available bone fixation pins or wires. We further question whether the LINK™ Bone Pins are integral to the service furnished as it is unclear, based on the information provided in the application, whether any LINK™ Bone Pins are included in the LINK™ External Fixator packaging, or if they are packaged and sold separately from the LINK™ External Fixator. With respect to the LINK™ Cover, because the applicant stated that the LINK™ Cover is a separate removable silicon elastomer cover that protects the LINK™ and the patient from the pin and wire ends and does not play a role in providing compression, as such, we also question if the LINK™ Cover is integral to the service furnished. We are interested in additional information about these components of the LINK™ External Fixator, including whether the components are required to furnish or deliver the primary procedure with which it is used and if the components can be substituted with other commercially available products.

With respect to whether the LINK™ External Fixator comes in contact with human tissue and is surgically inserted or implanted, we note that, per the applicant, the LINK™ Bone Pins (or other bone pins or wires) are the only components that come in contact with human tissue and are surgically implanted or inserted into the patient. Per the applicant, the LINK™ component remains outside the body and acts like a spring on skin penetrating bone fixation pins to reduce and provide continuous compression at the bone healing interface. We further note that, according to the applicant, the LINK™ Cover is a separate, removable cover that does not come in contact with and is not surgically implanted or inserted into the patient. Therefore, we believe the LINK™ and the LINK™ Cover components of the LINK™ External Fixator do not come into contact with human tissue and are not surgically inserted or implanted as required by § 419.66(b)(3).

We are inviting public comment on whether the LINK™ External Fixator meets the eligibility criterion at § 419.66(b)(3).

Regarding the eligibility criterion at § 419.66(b)(4), based on the applicant's description, we question whether the LINK™ Bone Pins could be considered a supply furnished incident to a service. First, we question the role of LINK™ Bone Pins in creating surgical openings for access to bone to accomplish the fixation provided by the LINK™. In the CY 2001 OPPS interim final rule (65 FR 67804 through 67805), we stated that we consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. Based on the information provided on the application, we are unclear if the LINK™ Bone Pins (or other bone fixation pins or wires) are placed through a previously created surgical opening or if they are directly inserted through skin and soft tissue to access bone. We would welcome information regarding whether, when, and how an incision is created during placement of the LINK™ External Fixator. Second, as discussed previously with respect to criteria at § 419.66(b)(3), we note that it is unclear whether the LINK™ Bone Pins may be replaced with other commercially available bone fixation pins or wires. We are seeking clarification about whether the LINK™ Bone Pins can be substituted with other commercially available products. We question whether LINK™ Bone Pins may be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

We are inviting public comment on whether the LINK™ External Fixator meets the eligibility criterion at § 419.66(b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), the applicant stated that the existing pass-through code of C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the LINK™ External Fixator because the category does not include fixators with the LINK™'s shape-changing, spring-like design that stores elastic mechanical energy allowing it to provide continuous dynamic compression, which pulls bones together and closes gaps formed by bone resorption or inadvertent mechanical loading and stimulates mesenchymal stem cells to differentiate along an osteogenic pathway to form bone and cartilage. In contrast, the applicant stated that traditional external fixators included in C1713 are static, and therefore, do not readjust or impart compression or distraction forces to enhance bone healing as the LINK™ does.

Based on the description the applicant provided, the LINK™ External Fixator is an external fixator that attaches to pins inserted into the bone principally with the intent to facilitate stabilization or oppose bone-to-bone contact, and therefore, could be appropriately described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). Further, C1713 does not describe the type of fixation or specify the type of compression created by the device. Specifically, we believe that the pass-through payment category C1713 may appropriately describe the LINK™ External Fixator because C1713

[50] We note that the applicant selected the APC level device offset amount of $0.19 for APC 5111 found in CY 2025 NFRM APC Offset File. Beginning in CY 2017, we calculate the device offset amount at the HCPCS code level instead of the APC level (81 FR 79657). We note the HCPCS code level device offset amounts for the HCPCS codes provided by the applicant are available in Addendum P to the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912). For our calculation, we selected the HCPCS level device offset amount of $50.18 related to HCPCS 28899 in APC 5111 found in Addendum P. Based on our initial assessment for this proposed rule, using the device offset amount of $50.18 would result in the LINKT External Fixator meeting the cost significance requirements.

describes implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact, which is consistent with the LINK™ External Fixator description. We note that we do not establish pass-through device categories for the purpose of describing specific devices, rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we believe that the LINK™ External Fixator may be appropriately described by C1713.

We are inviting public comment on whether the LINK™ External Fixator meets the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we have the following concerns regarding whether the LINK™ External Fixator meets the substantial clinical improvement criterion. Specifically, we are concerned that the applicant did not (1) clearly identify the patient population that is unresponsive to, or ineligible for, currently available treatments that can only be treated with the LINK™ External Fixator and provide corresponding supporting evidence; (2) provide sufficient evidence of the LINK™ External Fixator's effect on recovery time, adverse events, pain, or any other clinical outcomes; or (3) submit evidence that the LINK™ External Fixator substantially improves the diagnosis or treatment of an illness when compared to other available treatments.

First, the applicant asserted that the LINK™ External Fixator offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, but did not identify a patient population that can only be treated with the LINK™ External Fixator. Instead, the applicant stated that bone fixation for those who have infected sites, metal allergies, anesthesia sensitivity, skin pathology, or other co-morbidities (such as diabetes, neuropathy, or a compromised immune system) can be treated with the LINKÔ External Fixator due to the minimally invasive nature of bone fixation the nominated device provides. While, according to the applicant, these patients can be treated with the LINK™ External Fixator, the applicant did not explain why other available devices, such as the nitinol bone staple, mini-rail external fixator, and Genxfix External Fixation (the LINK™ External Fixator's predicate device), would not be available treatment options for this patient population. We welcome additional information and supporting evidence regarding a patient population that can only be treated with the LINKÔ External Fixator and not with another existing device.

Further, we note that no evidence was provided to support the applicant's claim that the LINK™ External Fixator significantly improves clinical outcomes compared to currently available treatments. We note that the applicant provided one document that describes the LINK™ External Fixator's uses and technical features and a second document that summarizes the principles of minimizing surgical trauma, application of continuous dynamic compression, and avoidance of permanent implants, which the applicant asserted are benefits associated with the nominated device, but did not provide any studies assessing the clinical outcomes of using the LINK™ External Fixator. Additionally, while the LINK™ External Fixation Independent Clinical Research Support document provided with the application includes citations that appear to represent studies related to internal and external fixation approaches, we cannot evaluate sources that are cited but not included as part of the application.

Moreover, we note that the applicant did not provide any evidence comparing the LINK™ External Fixator's clinical outcomes to those of other available treatment options, such as the Genxfix External Fixator (the predicate device), nitinol bone staple, Mini-Rail™ External Fixator, Hoffman® External Fixator System, or MaxFrame™. Specifically, FDA determined that the LINK™ External Fixator is substantially equivalent to a legally marketed device, the Genxfix External Fixator (the LINK™ External Fixator's predicate device), which received 510(k) clearance on December 28, 2016. The LINK™ External Fixator's FDA 510(k) summary indicated that the two devices share similar technological characteristics and that the LINK™ External Fixator differs only in its fixator utilizing a shape-changing spring rather than a shape-changing power screw and clamps to act on pins and wires as the Genxfix External Fixator does. We believe that further investigation with comparators would be helpful to determine whether the device demonstrates substantial clinical improvement over currently available treatments in the clinical setting where it is most likely to be used. To demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published, peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

We further note that dynamic digital external fixators made from readily available hardware (such as k-wires and dental rubber bands) have been in use for decades.[51] Since these external fixators appear to apply dynamic forces in the treatment of hand bone fractures, we question whether these devices may treat some of the same conditions in a similar manner and clinical setting as the LINK™ External Fixator, and therefore, whether the LINK™ External Fixator represents a substantial clinical improvement over these longstanding treatment options.

We are inviting public comment on whether the LINK™ External Fixator meets the substantial clinical improvement category criterion at § 419.66(c)(2).

We also are inviting public comment on whether the LINK™ External Fixator meets the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the LINK™ External Fixator meets the new device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for the LINK™ External Fixator for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the LINK™ External Fixator for CY 2027.

(c) Santreva™-ATK Endovascular Revascularization Catheter

AngioSafe®, Inc. submitted an application for a new device category for transitional pass-through payment status for the Santreva™-ATK Endovascular Revascularization Catheter (Santreva™-ATK Catheter) for CY 2027. According to the applicant, the Santreva™-ATK Catheter is an energy and wire-free platform for simultaneous intraplaque crossing and revascularization of complex occlusive peripheral artery disease, intended for facilitating intraluminal placement of guidewires beyond stenotic lesions.

[51] Chauhan, A., Sikora-Klak, J., & Abrams, R. (2018). Dynamic ''homemade'' digital external fixators for proximal interphalangeal joint injuries: Surgical technique. *The Journal of Hand Surgery,* 43(9), 875.E1–875.E12. *https://www.jhandsurg.org/article/S0363-5023(17)31675-1/fulltext/.*

Table 42 provides an overview of the device category for the transitional pass-through payment status application for the Santreva™-ATK Catheter and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at *https://mearis.cms.gov/public/publications/device-ptp/DEP260302QH9AE.*

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TABLE 42: SANTREVA™-ATK CATHETER APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	*FDA Marketing Authorization:* 510(k) clearance - September 22, 2025 *Application submitted to CMS*: March 2, 2026	No concerns.
FDA Indication	The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is percutaneously inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category code C1887 (catheter, guiding (may include infusion/perfusion capability)) does not describe the device.	See following discussion.
Cost Criteria	The cost of the Santreva™-ATK Catheter is $3,000.00. For cost significance requirements: HCPCS code: 37263 APC code: 5192 CY 2026 device offset amount: $2,314.89 CY 2026 APC payment rate: $5,814.84 Requirement #1: ($3,000.00 / $5,814.84) x 100 = 51.59%. Requirement #2: ($3,000.00 / $2,314.89) x 100 = 129.60%. Requirement #3: (($3,000.00 - $2,314.89) / $5,814.84) x 100 = 11.78%.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: Substantially improved mechanism; simultaneous crossing and revascularization Claim #2: Substantially improved safety: no periprocedural injury and reduced need for adjunctive plaque modification interventions with known adverse events Claim #3: Substantially improved complex lesion crossing Claim #4: Substantially improved crossing success in severely calcified lesions Claim #5: Substantial lumen gain while crossing complex lesions, delivering positive outcomes of multiple currently reimbursed maneuvers Claim #6: Predominantly intraplaque crossing and recanalization, preserving vessel wall integrity Claim #7: Substantial improvement in clinical condition and quality of life of patients Claim #8: Substantial improvement for physicians in day-to-day clinical practice Provided 1 published study assessing the technology, 19 published studies and articles assessing comparator technologies, and 31 background documents.	See following discussion.

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We are inviting public comment on whether the Santreva™-ATK Catheter meets the newness criterion at § 419.66(b)(1) and the eligibility criteria at § 419.66(b)(3) and (b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), per the applicant, the existing pass-through code C1887 (Catheter, guiding (may include infusion/perfusion capability)) does not appropriately describe the Santreva™-ATK Catheter, because C1887 does not reflect the full scope of the device's function or the significant clinical improvement associated with the Santreva™-ATK Catheter, which facilitates the placement of guidewires beyond stenotic lesions by laterally cutting and then compressing plaque, to form an intraluminal channel to restore blood flow.

Based on the description the applicant provided, the Santreva™-ATK Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including CTOs, in the femoropopliteal (arterial) peripheral vasculature, and therefore, may be appropriately described by C1887 (Catheter, guiding (may include infusion/perfusion capability)). Specifically, we believe the pass-through payment category C1887 may describe the Santreva™-ATK Catheter because the pass-through payment category includes guiding catheters and the Santreva™-ATK Catheter's primary function of crossing peripheral stenotic lesions to establish a revascularization pathway appears to be the same function performed by device described in C1887. In addition, per the applicant, the Santreva™-ATK Catheter is introduced and removed prior to final treatment, which is also consistent with the use of the guiding catheters described in C1887. We note that we do not establish pass-through device categories for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we believe the Santreva™-ATK Catheter may be appropriately described by C1887. We are inviting public comment on whether the Santreva™-ATK Catheter meets the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we have the following concerns regarding whether the Santreva™-ATK Catheter meets the substantial clinical improvement criterion. First, we note that the applicant submitted a single study evaluating the Santreva™-ATK Catheter in support of all eight substantial clinical improvement claims: Banerjee et al. (2026) [52]. The applicant provided an additional study, Saratzis et al. (2026),[53] which we consider to be reference material established by experts to define vessel preparation, core aims, and usage. We therefore do not believe this evidence directly supports the claims of improved mechanism compared to other existing devices or techniques that facilitate wire crossing.

The Banerjee et al. (2026) study analyzed the use of the Santreva™-ATK Catheter in 74 patients with Rutherford class 2 through 5 peripheral arterial disease and de novo femoropopliteal CTOs less than or equal to 30 centimeters in length. The primary outcome of the study was clinical success, defined as device-facilitated guidewire placement into the distal true lumen of the femoropopliteal CTO without device-related major adverse events through hospital discharge or within 24 hours post-procedure (whichever occurred first). We have several concerns with this study.

First, we are concerned about the study's small sample size of 74 patients. Peripheral artery disease (with or without CTO) affects approximately 12 million adults over the age of 40 in the U.S.[54] Based on the small sample size compared to the disease prevalence, we question whether the results of the study are generalizable to the broader Medicare population. Also, the study is single-arm with no comparator group, which limits the ability to assess whether the Santreva™-ATK Catheter demonstrates improved outcomes compared to other available technologies. In addition, we note that the Banerjee et al. (2026) study included patients with Rutherford classifications 2 (moderate claudication) through 5 (minor tissue loss), a measure which represents clinically distinct disease severities, but did not stratify outcomes by Rutherford class. As a result, it is difficult to interpret performance across clinically relevant severity subgroups, and to assess whether the Santreva™-ATK Catheter substantially improved complex lesion crossing, lumen gain while crossing complex lesions, and clinical condition and quality of life of patients. Furthermore, we note that the study's 30-day follow-up period limits our ability to evaluate periprocedural injury, predominant intraplaque crossing and recanalization, and clinical condition and quality of life of patients. Specifically, the 30-day follow-up in Banerjee et al. (2026) is insufficient to assess vessel wall integrity and recanalization outcomes. These outcomes may require a minimum of 12 months of follow-up to evaluate meaningfully as existing evidence demonstrates that femoropopliteal CTO interventions are associated with higher rates of reintervention at 12 months compared to non-CTO femoropopliteal interventions, indicating that clinically meaningful vessel wall outcomes continue to emerge beyond the 30-day periprocedural period.[55] Lastly, we are concerned that the study reports procedural success, focusing on safety and effectiveness, but does not isolate the contribution of simultaneous crossing from that of revascularization to patient outcomes. This limits our ability to evaluate the claims of improved mechanism of crossing and revascularization, improved safety with no periprocedural injury and reduced need for adjunctive plaque modification interventions with known adverse events, and improved complex lesion crossing. We note that the Santreva™-ATK Catheter is designed to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including CTOs, but requires a subsequent intervention, such as stent placement, atherectomy, or balloon angioplasty to achieve clinical improvement. Given that it is only a step in a larger revascularization procedure, it is unclear how the Santreva™-ATK Catheter

[52] Banerjee, S., Metzger, C., Thatipelli, M., Ramaiah, V.G., Sayfo, S., Das, T., Tsai, S., Hyder, O., Shammas, N. W., Bunte, M., Nseir, G., Thomas, A., Beasley, R., Bosarge, C., Gagne, P., Kwolek, C., Rao, S., Novak, S., Pershad, A., Walker, C., & Soukas, P. (2026). Safety and effectiveness of the Santreva™-ATK endovascular revascularization catheter in the RESTOR–1 peripheral CTO crossing pivotal study. *The American Journal of Cardiology.* Advance online publication. *https://doi.org/10.1016/j.amjcard.2026.01.007.*

[53] Saratzis, A., Patrone, L., Secemsky, E.A., Dua, A., Zayed, H., Torsello, G., Van Herzeele, I., Stavroulakis, K., & VPAD collaborators (2026). Use of Vessel Preparation in Endovascular Peripheral Arterial Disease (PAD) Interventions: A Global Qualitative Analysis. *Journal of endovascular therapy: an official journal of the International Society of Endovascular Specialists,* 15266028261424732. Advance online publication. *https://doi.org/10.1177/15266028261424732.*

[54] Cleveland Clinic. (n.d.). *Peripheral artery disease (PAD).* Cleveland Clinic. *https://my.clevelandclinic.org/health/diseases/17357-peripheral-artery-disease-pad .*

[55] Tsai, S., Liu, Y., Hoang, L., Vu, M., Lu, H., Ramanan, B., Fernandez Vazquez, D., Rosol, Z., Sayfo, S., Alaiti, M.A., Koutakis, P., Brilakis, E.S., Shishehbor, M.H., & Banerjee, S. (2023). Comparative outcomes of interventions for femoropopliteal chronic total occlusion versus non-chronic total occlusion lesions from the multicenter XLPAD registry. *Journal of the American Heart Association,* 12(12), e028425. *https://www.ahajournals.org/doi/10.1161/JAHA.122.028425.*

independently contributes to the clinical outcomes asserted.

Additionally, we believe that the Santreva™-ATK Catheter may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to other available treatments. We note that there are currently available treatments for facilitating the intraluminal placement of conventional guidewires across stenotic lesions in the femoropopliteal peripheral vasculature, including the Crosser™ Catheter S6 and the Viance™ Crossing Catheter.[56] While the applicant included these existing treatments in comparator tables, the applicant did not explain how the Santreva™-ATK Catheter's improves patient-centered outcomes compared to other currently available CTO crossing devices. In addition, the applicant submitted three articles as comparator evidence, two publications on restenosis after directional atherectomy for lower-extremity peripheral artery disease (Krishnan et al., 2012; Tarricone, et al., 2015),[57 thnsp;58] and one report evaluating FlowCardia's Crosser device for CTO recanalization in the PATRIOT study (Endovascular Today, 2009).[59] However, we believe the Krishnan and Tarricone articles would be more appropriately characterized as background literature as they do not establish a performance benchmark against which the Santreva™-ATK Catheter can be meaningfully compared. Furthermore, the source cited in a trade magazine that references the PATRIOT study is not the actual peer-reviewed study. As such, we believe that this evidence has limited value for the purposes of comparison. We would welcome additional information that includes longer follow-up periods and comparator evidence that includes prospective studies of lesion-specific crossing devices that establish a meaningful performance benchmark for crossing success, safety, and durability.

Additional information about how the Santreva™-ATK Catheter leads to significantly improved patient-centered outcomes compared with currently available CTO crossing devices would help our assessment of whether the Santreva™-ATK Catheter demonstrates substantial clinical improvement over existing technologies. To demonstrate substantial clinical improvement over existing technologies, we consider supporting evidence, preferably published, peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or more rapid beneficial resolution of the disease process, compared to the standard of care.

With regard to the second and third claims, the applicant provided slide decks with comparative tables, however, the tables do not identify the specific studies or datasets from which the comparator values originated. Without access to the underlying sources, we are unable to evaluate study methodologies, patient selection, lesion characteristics, endpoint definitions, or follow-up duration, and therefore cannot determine whether any observed differences reflect true improvements attributable to the Santreva™-ATK Catheter.

With respect to the fifth claim, the applicant asserted that the Santreva™-ATK Catheter is a substantial clinical improvement over current crossing devices and algorithms, which require adjunct debulking or plaque modification devices for lumen gain. However, all patients in Banerjee et al. (2026) subsequently underwent a definitive revascularization procedure, making it difficult to isolate the clinical contribution of luminal gain achieved during crossing. Additionally, the supporting evidence does not demonstrate how the reported luminal gain represents an improvement over, or translates to better clinical outcomes than, other plaque modifying devices or techniques that achieve comparable luminal gain.

Regarding the seventh claim that the Santreva™-ATK Catheter substantially improves the clinical condition and quality of life of patients, the applicant submitted the Banerjee et al. (2026) study but provided no comparator data. We are concerned that the submitted evidence does not differentiate device use outcomes from the overall revascularization procedure outcomes. Specifically, the Santreva™-ATK Catheter requires a subsequent intervention, such as stent placement, atherectomy, or balloon angioplasty, to achieve clinical improvement, and it is, therefore, unclear how the Santreva™-ATK Catheter independently contributes to the clinical outcomes asserted in this claim. We are also concerned that the 30-day follow-up in Banerjee et al. (2026) may not be sufficient to comprehensively assess clinical condition and quality of life outcomes, which may require longer assessment. We would be interested in additional information to determine whether the Santreva™-ATK Catheter independently contributes to downstream, patient-level clinical outcomes independent of the overall revascularization procedure.

With regard to the eighth claim that the Santreva™-ATK Catheter offers a substantial improvement for physicians in day-to-day clinical practice, we note that this is a matter of physician workflow rather than measurable clinical outcomes for patients. We therefore question whether the evidence provided, which primarily focuses on the lack of device-related major adverse events and lesion crossing time, supports the applicant's claim of substantial clinical improvement, and request clarification on how the evidence provided directly relates to the applicant's claims of improved clinical outcomes.

We also note the applicant included supplemental information in which the applicant described atheroplasty as a novel paradigm that integrates intraplaque traversal, lateral plaque compression, channel creation, and immediate distal perfusion. This information was not linked to a specific claim of substantial clinical improvement. To the extent the application includes materials that are not tied to a specific substantial clinical improvement claim, we are unable to evaluate that content under the substantial clinical improvement criteria.

We are inviting public comment on whether the Santreva™-ATK Catheter meets the device category criterion at § 419.66(c)(2).

We also are inviting public comment on whether the Santreva™-ATK Catheter meets the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the

[56] EV Today. (n.d.). *CTO crossing devices. https://evtoday.com/device-guide/us/cto-crossing-devices.*

[57] Krishnan, P., Baber, U., Purushothaman, K.R., Purushothaman, M., Wiley, J., Tarricone, A., Mehran, R., Kovacic, J., Kim, M., Moreno, P., Kini, A., Dangas, G., & Sharma, S. (2012). Histopathologic evidence of adventitial cuts predicts restenosis after directional atherectomy of lower extremity peripheral arterial disease: Results from a randomized, open label, investigator initiated trial comparing intravascular ultrasound guided atherectomy to angiography guided atherectomy in peripheral vascular interventions for TASC's A, B lesions (UTOPIA) pilot study [Abstract]. *Journal of the American College of Cardiology,* 59(13), E2083.

[58] Tarricone, A., Ali, Z., Rajamanickam, A., Gujja, K., Kapur, V., Purushothaman, K.R., Purushothaman, M., Vasquez, M., Zalewski, A., Parides, M., Overbey, J., Wiley, J., & Krishnan, P. (2015). Histopathological evidence of adventitial or medial injury is a strong predictor of restenosis during directional atherectomy for peripheral artery disease. *Journal of Endovascular Therapy,* 22(5), 712–715. *https://doi.org/10.1177/1526602815597683/.*

[59] Endovascular Today. (2009, October 22). PATRIOT evaluates FlowCardia's Crosser to mediate CTO recanalization. *http://evtoday.com/2009/10/eNews102909_07.htmwhy.*

Santreva™-ATK Catheter meets the new device category eligibility criteria; therefore, we propose to deny transitional pass-through payment status for the Santreva™-ATK Catheter for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the Santreva™-ATK Catheter for CY 2027.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40 percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4. of the CY 2026 OPPS/ASC proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3. of the CY 2026 OPPS/ASC proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria as listed. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b. of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive- status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3. and IV.C.4. of this proposed rule.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Proposed Device-Intensive Procedure Policy

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to

30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believed allowing these additional procedures to qualify for device-intensive status would help ensure these procedures receive more appropriate payment in the ASC setting, which would help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, or has received an FDA IDE and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

++ Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 83 FR 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94214

through 92419), we finalized a change to our methodology for applying default device offset percentages for new device-intensive procedures. Under our previous policy, if a new CPT/HCPCS code did not have available claims data, either from the new HCPCS code or any predecessor code or clinically-similar code that uses the same device, and the CPT/HCPCS code otherwise met our criteria for device-intensive status, we would apply a default device offset percentage of 31 percent. However, we were aware of certain situations where the default device offset amount might not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. A potential large difference between the default device offset amount and the device portion of similar devices might impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPPS and to set payment rates for device-intensive procedures under the ASC payment system. Therefore, for CY 2025 and subsequent CYs, we finalized our proposal to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new CPT/HCPCS codes that both describe a procedure that requires the surgical implantation or insertion of a single-use device that exceeds 30 percent of the procedure's cost and that meets our requirements of a device as described here and lack claims data (from either the new HCPCS code or any predecessor code or clinically-similar code that uses the same device), we would apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We stated that we still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data, we believe the APC-wide average device offset percentage is, in many cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we finalized our modification to our default device offset percentage for new device-intensive procedures. This methodological change was finalized for both the OPPS and ASC Payment System for CY 2025 and subsequent CYs and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 92414 through 92419), we stated that we were persuaded by commenters that the lack of a device edit for device-intensive procedures, particularly new technologies, might lead to an underreporting of device costs and total procedure costs and potentially impede beneficiary access to such new technologies over time. Therefore, in addition to finalizing a modification to our device edits policy for CY 2025, we finalized a modification to our device offset percentage calculation. For procedures subject to our modified device edits policy for CY 2025 that cannot report modifier ''CG'' to bypass this claims processing edit, the device offset percentages calculated (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. We stated that we believed that hospital outpatient claims that report a device code with such procedures provide, in general, a more accurate representation of the procedures' total costs. We also finalized, for purposes of determining device offset percentages, that we will not use claims data from procedures that had a status indicator of ''E1'' during the calendar year we are using for ratesetting and determining device offset percentages. Lastly, we refined our process for applying device offset percentages to use available claims data from predecessor codes annually, rather than the first year of the successor code's activation date, until we have available claims data from the successor code. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53673 through 53679), we finalized our proposal to continue these policies for CY 2026.

We propose to continue these policies for CY 2027. Specifically, we propose to continue use of HCPCS code-level device-intensive determination and three criteria to designate device-intensive procedures, in accordance with existing policies. We also propose to continue our device-intensive procedure policy, our proposed use of CY 2025 claims information for determining device offset percentages and assigning device-intensive status, and our proposed default device offset policy for determining device offset percentages in the absence of claims data for device-intensive procedures. As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent (or the APC-wide default offset percentage) for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care electronically at *outpatientpps@cms.hhs.gov.* Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2027 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2027 OPPS/ASC proposed rule on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) was reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)), will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy

for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent- years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81758 through 81759), we finalized our proposal to establish a procedure-to-device edit for the procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures—CPT codes 0308T and 0616T, 0617T, and 0618T. (We note that CPT codes 0617T and 0618T were deleted effective January 1, 2025 and CPT code 0616T was deleted effective January 1, 2025 and replaced with new CPT code 66683.) We have noted that interested parties have previously recommended in past rulemaking that we reestablish all our previous procedure-to-device edits, but we do not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). This APC represents a unique situation—the APC (which was the Level 5 Intraocular APC in previous years) had been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than $15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. In the CY 2025 OPPS/ASC final rule with comment period, we finalized to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent years.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 92419 through 92422), we finalized a modification to our device edits policy. While historically our device edits policy has only applied to procedures that are device-intensive based on the most recent claims data available, commenters had raised concerns about hospitals underreporting device costs in years when certain device-intensive procedures had lost device-intensive status because the device portion of a procedure can fluctuate above and below our device-intensive threshold of 30 percent. Commenters indicated to us that the presence of the device edit requirement can have a significant impact on the device portion and geometric mean cost of a procedure, particularly for newer technologies. Therefore, for CY 2025 and subsequent CYs, we finalized a policy to apply our device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, we finalized a policy to reinstate our device edits policy for procedures that have been device-intensive since we began assigning device-intensive status at the HCPCS code level on January 1, 2017. We believed that by applying our device edit policy to procedures that were device-intensive on or after January 1, 2017, we might continue to receive device cost information for relatively new procedures with limited claims data, which may have been impacted by our policy to require that only existing device-intensive procedures be subject to our device edits policy.

We are not proposing any changes to our device edit policy for CY 2027.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining

the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including chapter 4, section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2027.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act (42 U.S.C. 1395*l*(t)(6)) provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. A ''biological'' as used in this proposed rule, and as codified at 42 CFR 414.802 and 414.902 includes a ''product licensed under section 351 of the PHS [Public Health Service] Act''. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as a Hospital Outpatient Department (HOPD) service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Drugs and biologicals pass-through applications are accepted and approved on a quarterly basis in which pass-through payments for approved applications could begin on the next available OPPS quarterly update. Furthermore, our current policy, which was finalized in CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), is to allow for quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible to allow, on a prospective basis, for the maximum pass-through payment period without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals. Proposed CY 2027 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available on the CMS website).[60]

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act (42 U.S.C. 1395u(o)) for the drug or biological exceeds the portion of the otherwise applicable Medicare Outpatient Department (OPD) fee schedule that the Secretary determines is associated with the drug or biological. The regulations at 42 CFR 419.64(d) specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the Ambulatory Payment Classification (APC) payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act (42 U.S.C. 1395w–3a) establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

The pass-through application [61] and review process for drugs and biologicals

[60] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[61] To apply for OPPS transitional Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC), applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS–10008) is currently approved under OMB control number of 0938–0802 and has an expiration date of July 31, 2027.

is described on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc.*

2. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2026

There are 49 drugs and biologicals for which pass-through payment status expires by December 31, 2026, as listed in Table 43. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2023 through December 31, 2026. In accordance with the policy finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662) and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals[62] that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year, which is proposed to be $140 for CY 2027 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for high-cost diagnostic radiopharmaceuticals, we would provide separate payment when their per day cost is greater than the threshold we propose to adopt of $665). These policies are discussed further in section V.B.1. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2. of this proposed rule.

We welcome public comments on the status indicator for expiring pass-through drugs and biologicals, in accordance with our existing policies on packaged drugs, biologicals, and radiopharmaceuticals, including the threshold packaging policy.

[62] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period for more information regarding this policy.

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TABLE 43: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026
J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026
J2329	Injection, ublituximab-xiiy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	Fecal microbiota, live - jslm, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	Injection, sodium thiosulfate,100 mg	G	9119	07/01/2023	6/30/2026
J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026
J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0184	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy	G	0732	10/01/2023	9/30/2026
J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy	G	0733	10/01/2023	9/30/2026
J9321	Injection, epcoritamab-bysp, 0.1 mg	G	9250	10/01/2023	9/30/2026
A9608	Flotufolastat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
J1304	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
J2799	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026
J7353	Anacaulase-bcdb, 8.8% gel, 1 gram	G	0742	01/01/2024	12/31/2026
J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/mL vector genomes, per 0.1 mL	G	0716	01/01/2024	12/31/2026
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)	G	0707	01/01/2024	12/31/2026
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie	G	0709	01/01/2024	12/31/2026
J0177	Injection, aflibercept hd, 1 mg	G	0704	01/01/2024	12/31/2026
J2782	Injection, avacincaptad pegol, 0.1 mg	G	0705	01/01/2024	12/31/2026
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	G	0703	01/01/2024	12/31/2026
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	G	0714	01/01/2024	12/31/2026
J1323	Injection, elranatamab-bcmm, 1 mg	G	0708	01/01/2024	12/31/2026
J9286	Injection, glofitamab-gxbm, 2.5 mg	G	0720	01/01/2024	12/31/2026
J0174	Injection, lecanemab-irmb, 1 mg	G	9157	01/01/2024	12/31/2026
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg	G	0715	01/01/2024	12/31/2026
J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity	G	0702	01/01/2024	12/31/2026
J0349	Injection, rezafungin, 1 mg	G	9267	01/01/2024	12/31/2026
J9333	Injection, rozanolixizumab-noli, 1 mg	G	0721	01/01/2024	12/31/2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J3055	Injection, talquetamab-tgvs, 0.25 mg	G	0706	01/01/2024	12/31/2026
J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2 × 10^13 vector genomes	G	0713	01/01/2024	12/31/2026
J0217	Injection, velmanase alfa-tycv, 1 mg	G	0710	01/01/2024	12/31/2026
J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose	G	0717	01/01/2024	12/31/2026

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3. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in or Continuing Through CY 2027

We propose to end pass-through payment status in CY 2027 for 28 drugs and biologicals. These products, listed in Table 44, were initially approved for pass-through payment status between April 1, 2024 and January 1, 2025. We also propose to continue pass-through payment status through CY 2027 for 45 drugs and biologicals, listed in Table 45, which were initially approved for pass-through payment status between April 1, 2025 and April 1, 2026. The APCs and Healthcare Common Procedure Coding System (HCPCS) codes for pass-through drugs and biologicals are assigned status indicator ''G'' (Pass-Through Drugs and Biologicals) in Addenda A and B to this proposed rule (which are available on the CMS website).[63] The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator ''G'' only for the duration of their pass-through status.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2027, we are continuing our policy to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP, as applicable. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2027. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, a $0 pass-through payment amount will continue to be paid for pass-through drugs and biologicals under the CY 2027 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is generally ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals[64] below the applicable cost threshold that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount will continue to be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate will generally continue to be ASP plus 6 percent for CY 2027, minus a payment offset for the portion of the otherwise applicable OPPS payment that the Secretary determines is associated with the drug or biological. We note that if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPPS payment amounts for them.

We note that in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we modified the regulation text at 42 CFR 419.2(b)(15) to specify that only those diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year are policy-packaged. Meaning, for those diagnostic radiopharmaceuticals that are below the diagnostic radiopharmaceutical packaging threshold, for purposes of pass-through co-insurance calculations, they are treated like policy packaged drugs. For those diagnostic radiopharmaceuticals above the diagnostic radiopharmaceutical packaging threshold, they are not packaged, and are not considered policy packaged; therefore, for purposes of pass-through co-insurance calculations, they are treated like separately payable drugs assigned to an APC. Accordingly, a $0 pass-through payment amount is assigned consistent with our policy described previously in this section for separately payable drugs assigned to an APC.

We will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY 2027 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass- through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2027, consistent with our CY 2026 policy for diagnostic and therapeutic radiopharmaceuticals, we will continue to provide payment for both diagnostic and therapeutic

[63] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[64] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period for more information regarding this policy.

radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2027, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we will continue to provide pass-through payment at WAC plus 3 or 6 percent, the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 or 6 percent payment policy can be found in section V.B.2.a. of this proposed rule. If WAC information also is not available, we will continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 44 for the list of drugs and biologicals with pass-through payment status expiring during CY 2027 and Table 45 for the list of drugs and biologicals with pass-through payment status continuing through CY 2027.

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TABLE 44: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2027

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7171	J7171	Injection, adamts13, recombinant-krhn, 10 iu	G	0727	04/01/2024	03/31/2027
J9248	J9248	Injection, melphalan (hepzato), 1 mg	G	0730	04/01/2024	03/31/2027
J2267	J2267	Injection, mirikizumab-mrkz, 1 mg	G	0728	04/01/2024	03/31/2027
J2277	J2277	Injection, motixafortide, 0.25 mg	G	0729	04/01/2024	03/31/2027
J3247	J3247	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment	G	0748	07/01/2024	06/30/2027
J3393	J3393	Injection, betibeglogene autotemcel, per treatment	G	0746	07/01/2024	06/30/2027
J3263	J3263	Injection, toripalimab-tpzi, 1 mg	G	0745	07/01/2024	06/30/2027
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	G	0744	07/01/2024	06/30/2027
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram	G	0749	07/01/2024	06/30/2027
A9506	A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each	G	0760	07/01/2024	06/30/2027
J9028	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram	G	0767	10/01/2024	09/30/2027
J9345	J9345	Injection, retifanlimab-dlwr, 1 mg	G	9280	10/01/2024	09/30/2027
Q5133	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg	G	0786	10/01/2024	09/30/2027

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CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	G	0784	10/01/2024	09/30/2027
J9026	J9026	Injection, tarlatamab-dlle, 1 mg	G	0768	10/01/2024	09/30/2027
J9172	J9172	Injection, docetaxel (docivyx), 1 mg	G	0757	10/01/2024	09/30/2027
J9324	J9324	Injection, pemetrexed (pemrydi rtu), 10 mg	G	0782	10/01/2024	09/30/2027
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg	G	0761	10/01/2024	09/30/2027
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg	G	0737	10/01/2024	09/30/2027
A9615	A9615	Injection, pegulicianine, 1 mg	G	0772	10/01/2024	09/30/2027
J2601	J2601	Injection, vasopressin (baxter), 1 unit	G	0778	01/01/2025	12/31/2027
A9697	A9697	Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose	G	0814	01/01/2025	12/31/2027
J0175	J0175	Injection, donanemab-azbt, 2 mg	G	0765	01/01/2025	12/31/2027
Q5148	Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram	G	0811	01/01/2025	12/31/2027
J2468	J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms	G	0815	01/01/2025	12/31/2027
J0870	J0870	Injection, imetelstat, 1 mg	G	0813	01/01/2025	12/31/2027
J9329	J9329	Injection, tislelizumab-jsgr, 1mg	G	0816	01/01/2025	12/31/2027

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TABLE 45: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2027

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0138	J0138	Injection, acetaminophen 10 mg and ibuprofen 3 mg	G	2075	04/01/2025	03/31/2028
J3300	J3300	Injection, triamcinolone acetonide, preservative-free, 1 mg	G	1253	04/01/2025	03/31/2028
A9611	A9611	Flurpiridaz f 18, diagnostic, 1 millicurie	G	2065	04/01/2025	03/31/2028
Q5147	Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg	G	2068	04/01/2025	03/31/2028
J9072	J9072	Injection, cyclophosphamide (avyxa), 5 mg	G	0719	04/01/2025	03/31/2028
J9292	J9292	Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg	G	2076	04/01/2025	03/31/2028
J9054	J9054	Injection, bortezomib (boruzu), 0.1 mg	G	2066	04/01/2025	03/31/2028
Q2058	Q2058	Obecabtagene autoleucel, up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2061	04/01/2025	03/31/2028
Q2057	Q2057	Afamitresgene autoleucel up to 10 billion mage-a4 tcr positive t-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2067	04/01/2025	03/31/2028
J9276	J9276	Injection, zanidatamab-hrii, 2 mg	G	2062	04/01/2025	03/31/2028
J1326	J1326	Injection, zolbetuximab-clzb, 1 mg	G	2063	04/01/2025	03/31/2028
J7172	J7172	Injection, marstacimab-hncq, subcutaneous, 0.5 mg	G	2064	04/01/2025	03/31/2028
J9174	J9174	Injection, docetaxel (beizray), 1 mg	G	0841	07/01/2025	06/30/2028

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9382	J9382	Injection, zenocutuzumab-zbco, 1 mg	G	0853	07/01/2025	06/30/2028
Q5152	Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg	G	0846	07/01/2025	06/30/2028
J9011	J9011	Injection, datopotamab deruxtecan-dlnk, 1 mg	G	0835	07/01/2025	06/30/2028
J0614	J0614	Injection, treosulfan, 50 mg	G	0837	07/01/2025	06/30/2028
J9249	J9249	Injection, melphalan (apotex), 1 mg	G	0842	07/01/2025	06/30/2028
J9038	J9038	Injection, axatilimab-csfr, 0.1 mg	G	0839	07/01/2025	06/30/2028
J9289	J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy	G	0848	07/01/2025	06/30/2028
Q5100	Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg	G	0857	07/01/2025	06/30/2028
J9220	J9220	Injection, indigotindisulfonate sodium, 1 mg	G	0821	07/01/2025	06/30/2028
J0458	J0458	Injection, aztreonam/avibactam, 7.5 mg/2.5 mg (10 mg)	G	0878	10/01/2025	09/30/2028
J9256	J9256	Injection, nipocalimab-aahu, 3 mg	G	0893	10/01/2025	09/30/2028
J9326	J9326	Injection, telisotuzumab vedotin-tllv, 1 mg	G	0894	10/01/2025	09/30/2028
J3403	J3403	Revakinagene taroretcel-lwey, per implant	G	0897	10/01/2025	09/30/2028
Q5151	Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg	G	0852	10/01/2025	09/30/2028
A9616	A9616	Gallium ga-68 gozetotide (gozellix), diagnostic, 1 millicurie	G	0876	10/01/2025	09/30/2028
J7174	J7174	Injection, fitusiran, 0.04 mg	G	0889	10/01/2025	09/30/2028

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q9998	Q9998	Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg	G	0859	10/01/2025	09/30/2028
Q9999	Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg	G	0895	10/01/2025	09/30/2028
J0681	J0681	Injection, ceftobiprole medocaril sodium, 3 mg	G	0879	10/01/2025	09/30/2028
C9307	C9307	Injection, linvoseltamab-gcpt, 1 mg	G	0916	01/01/2026	12/31/2028
C9308	C9308	Injection, carboplatin (avyxa), 1 mg	G	0917	01/01/2026	12/31/2028
J1737	J1737	Injection, meloxicam (azurity), 1 mg	G	0898	01/01/2026	12/31/2028
J9184	J9184	Injection, gemcitabine hydrochloride (avyxa), 200 mg	G	0909	01/01/2026	12/31/2028
J9275	J9275	Injection, cosibelimab-ipdl, 2 mg	G	0915	01/01/2026	12/31/2028
J9282	J9282	Mitomycin, intravesical instillation, 1 mg	G	0913	01/01/2026	12/31/2028
Q5158	Q5158	Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg	G	0892	01/01/2026	12/31/2028
Q5160	Q5160	Injection, bevacizumab-nwgd (jobevne), biosimilar, 10 mg	G	0918	01/01/2026	12/31/2028
C9309	C9309	Injection, onasemnogene abeparvovec-brve, per treatment	G	0922	04/01/2026	03/31/2029
J3404	J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose	G	0924	04/01/2026	03/31/2029
J9183	J9183	Gemcitabine intravesical system, 225 mg	G	0926	04/01/2026	03/31/2029
J9277	J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph	G	0930	04/01/2026	03/31/2029
Q5162	Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg	G	0934	04/01/2026	03/31/2029

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We welcome public comments on the status indicator for expiring pass-through drugs and biologicals, in accordance with our existing policies on

packaged drugs, biologicals, and radiopharmaceuticals, including the threshold packaging policy.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $140 for CY 2026 (90 FR 53698).

Following the CY 2007 methodology, for the CY 2027 OPPS/ASC proposed rule, we propose to use the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2027 and round the resulting dollar amount ($142.40) to the nearest $5 increment, which yields a figure of $140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IGI. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations, we propose a packaging threshold for CY 2027 of $140 for drugs, biologicals, and therapeutic radiopharmaceuticals. We also propose that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 OPPS drug packaging threshold amount in the CY 2027 OPPS/ASC final rule with comment period.

We finalized in section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94238 through 94241) to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the packaging threshold for CY 2025 of $630. We also finalized that starting in CY 2026 and subsequent years, we would update this threshold by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). For the diagnostic radiopharmaceutical packaging threshold, we finalized using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPS drug packaging threshold. Specifically, we finalized that, starting with the CY 2026 rulemaking cycle, we would use the most recently available four quarter moving average PPI levels to trend the CY 2025 threshold amount forward from the third quarter of the data year (CY 2024) to the third quarter of the payment year (CY 2025) and round the resulting dollar amount to the nearest $5 increment. In the CY 2026 OPPS/ASC final rule, we finalized a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 threshold amount of $630 forward from the third quarter of CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest $5 increment. We believed using the most recently available forecast of the four quarter moving average PPI levels more appropriately updates the packaging threshold amount from CY 2025 to the current payment year moving forward. For this proposed rule, we propose to use the most recently available four quarter moving average PPI levels to trend the final CY 2025 $630 diagnostic radiopharmaceutical packaging threshold forward from the third quarter of CY 2025 to the third quarter of CY 2027 and round the resulting dollar amount ($667.44) to the nearest $5 increment, which yields a proposed radiopharmaceutical packaging threshold amount of $665 for CY 2027. We also propose that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 diagnostic radiopharmaceutical packaging threshold amount in the CY 2027 OPPS/ASC final rule with comment period.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Radiopharmaceuticals Under the Cost Thresholds

To determine the proposed CY 2027 packaging status for all nonpass-through drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2025 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2025 claims processed through December 31, 2025, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2027: anesthesia drugs; drugs, biologicals, and contrast agents and other drugs that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. Consistent with our policy described in section V.B.5. of this proposed rule, in situations where we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

To calculate the per day costs for drugs, biologicals, diagnostic radiopharmaceuticals, and therapeutic radiopharmaceuticals to determine their proposed packaging status for CY 2027, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we estimated payment rates for CY 2027 using the ASP methodology, (ASP plus 6 percent, which is the payment rate we proposed for separately payable drugs and biologicals), as discussed in more detail in section V.A.1. and V.B.2. of this proposed rule to calculate the proposed CY 2027 per day costs. We used the manufacturer-submitted ASP

data from the fourth quarter of CY 2025 (data that were used for payment purposes in the physician's office setting, effective April 1, 2026) to determine the proposed CY 2027 OPPS/ASC per day costs.

As is our standard methodology, for CY 2027, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2025 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2027 OPPS/ASC proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2026. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, and do not have an ASP-based payment rate, we did not use a payment rate based on WAC or AWP for those items, consistent with our policy described in section V.B.3.a. of this proposed rule. Instead, we used their arithmetic mean unit cost derived from the CY 2025 hospital claims data to determine their per day cost.
- For diagnostic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, we used their arithmetic mean unit cost derived from the CY 2025 hospital claims data to determine their per day cost. We did not use an ASP-based, WAC-based, or AWP-based payment rate for those items unless there was no arithmetic mean unit cost reported for the product, consistent with our proposed policy described in section V.B.3. of this proposed rule.
- For items other than diagnostic or therapeutic radiopharmaceuticals that did not have either an ASP-based payment rate, a payment rate based on WAC, or a payment rate based on AWP, we used the arithmetic mean unit cost of the items derived from the CY 2025 hospital claims data to determine their per day cost.

We propose to package drugs, biologicals, and therapeutic radiopharmaceuticals with a per day cost less than or equal to $140 and identify items with a per day cost greater than $140 as separately payable unless they are policy packaged. For diagnostic radiopharmaceuticals, we propose to package those items with a per day cost less than or equal to $665 and identify items with a per day cost greater than $665 as separately payable. Consistent with our past practice (72 FR 667580), we cross-walked historical OPPS claims data from the CY 2025 HCPCS codes that were reported to the CY 2024 HCPCS codes that we display in Addendum B to this proposed rule (which is available on the CMS website)[65] for proposed payment in CY 2027.

Our policy during previous cycles of OPPS rulemaking has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period (71 FR 68086; 78 FR75022; 89 FR 94238). We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year (71 FR 68086). Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2025, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2026, along with updated hospital claims data from CY 2025. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

We propose that payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the CY 2027 OPPS/ASC final rule with comment period would be based on ASP data from the second quarter of CY 2026. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2026. These payment rates would then be updated in the January 2027 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2027. For drugs and biologicals that do not currently have a payment rate based on ASP, WAC, or AWP, for therapeutic radiopharmaceuticals that do not currently have an ASP payment rate, and for all diagnostic radiopharmaceuticals, we will calculate their arithmetic mean unit cost from all of the CY 2025 claims data and updated cost report information available for the CY 2027 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the CY 2027 OPPS/ASC final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS final rule with comment period (69 FR 65780) is in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2027 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2027. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2027 and subsequent years, consistent with our historical practice, we propose to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2026 and that are proposed for separate payment in CY 2027, and that then have per day costs equal to or less than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule, would continue to receive separate payment in CY 2027.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2026 and that are proposed for separate payment in CY 2027, and that then have per day costs equal to or less than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule with comment period, would remain packaged in CY 2027.
- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2027 but that then have per-day costs greater than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs

[65] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

and hospital claims data used for the CY 2027 final rule, would receive separate payment in CY 2027.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are currently as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure including, but not limited to products, excluding skin substitutes, that aid wound healing; (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than the policy at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals that have a per day cost below the finalized diagnostic radiopharmaceutical packaging threshold that we discuss in section II.A.3. of this proposed rule, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) currently includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2027.

To propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2025 claims data and our pricing information, which is based on the ASP methodology, generally ASP plus 6 percent, across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the arithmetic mean unit cost available from the CY 2025 claims data to make the proposed packaging determinations for them: HCPCS 3471 (injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40,500 ml); and HCPCS code J7110 (Infusion, dextran 75,500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP methodology based payment rate, which is generally ASP plus 6 percent, per-unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2027 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2027 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2027 is displayed in Table 46.

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TABLE 46: PROPOSED HCPCS CODES TO WHICH THE CY 2027 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2027 HCPCS Code	CY 2027 Long Descriptor	Proposed CY 2027 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	E2
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	E2
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N

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We propose that our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2027 would also apply to diagnostic radiopharmaceuticals. This is because, as with drugs and biologicals, we believe that adopting standard HCPCS code-specific packaging determinations for radiopharmaceutical codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. To propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same diagnostic radiopharmaceutical, we would aggregate our CY 2025 claims data across all the HCPCS codes that describe each distinct diagnostic radiopharmaceutical to determine the mean units per day of the diagnostic radiopharmaceutical in terms of the HCPCS code with the lowest dosage descriptor. We would then analyze the aggregate per day cost of the diagnostic radiopharmaceutical to determine if the per day cost is less than or equal to the proposed CY 2026 diagnostic radiopharmaceutical packaging threshold of $665 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed CY 2027 diagnostic radiopharmaceutical packaging threshold of $665 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be separately payable). There are currently no diagnostic radiopharmaceuticals that this policy would apply to.

2. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the

Secretary, subject to any adjustment for overhead costs and considering the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of the Act. We refer to this alternative methodology as the ''statutory default''. Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to consider overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to consider the findings of the MedPAC study.[66]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we finalized a policy to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs; but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2025.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3 percent add-on in place of the 6 percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs, biologicals, and certain radiopharmaceuticals. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug, biological, or radiopharmaceutical under section 1847A(c)(4) of the Act. When WAC-based pricing is used for a drug, biological, or radiopharmaceutical, but not under section 1847A(c)(4) of the Act, the payment of WAC plus 6 percent would apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs, biologicals, and radiopharmaceuticals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not applied in determining payments for these separately payable drugs and biologicals.

Separately payable drug, biological, and radiopharmaceutical payment rates were listed in Addenda A and B to this proposed rule (available on the CMS website).[67] These addenda provide the proposed CY 2027 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals, with exceptions for certain radiopharmaceuticals previously discussed, and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for certain radiopharmaceuticals, these rates were based either on ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2026, or WAC, AWP, or the arithmetic mean unit cost from CY 2025 claims data and updated cost report information available for the proposed rule. For nonpass-through therapeutic radiopharmaceuticals, payment rates were based on ASP data or the arithmetic mean unit cost. We propose to pay separately at the arithmetic mean unit cost for diagnostic radiopharmaceuticals with per day costs above the proposed threshold; the

[66] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/June05_ch6.pdf.*

[67] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

payment rates proposed for qualifying diagnostic radiopharmaceuticals are entirely the arithmetic mean unit cost if available (see section II.A.3.c.(3) of this proposed rule, regarding payment policy of qualifying diagnostic radiopharmaceuticals). In general, these published proposed payment rates will not be the same as the actual January 2027 payment rates. This is because payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals with ASP information for January 2027 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2026 (July 1, 2026, through September 30, 2026) will be used to set the payment rates that are released for the quarter beginning in January 2027 in December 2026. In addition, in Addenda A and B to this proposed rule, payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals for which there was no ASP, WAC, or AWP information available for April 2026, as well as all separately payable diagnostic radiopharmaceuticals, were based on the arithmetic mean unit cost in the available CY 2025 claims data.

If new pricing information becomes available for payment for the quarter beginning in January 2026, we will price payment for these drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals based on their newly available information. Finally, there may be drugs, biologicals and therapeutic radiopharmaceuticals that had ASP, WAC, or AWP information available for the proposed rule (reflecting April 2026 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2027. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on the arithmetic mean unit cost data derived from CY 2025 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2027 payment purposes and were only illustrative of the CY 2027 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2027 OPPS/ASC proposed rule.

We note that payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on.

In CY 2025, we clarified that only ASP data or, if ASP data are not available, the arithmetic mean unit cost data, would be used to set payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals under the OPPS. For CY 2027, we are not proposing any changes to our policies for payment for separately payable therapeutic or diagnostic radiopharmaceuticals.

For CY 2027, we are not proposing any additional changes to our policies for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

b. Biosimilar Biological Products

In the CY 2024 OPPS/ASC final rule with comment period, we finalized the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid (88 FR 81783 through 81785). This policy allows for separate payment for biosimilars even if the biosimilar's per-day cost is below the packaging threshold if the biosimilar's reference product is separately paid. This policy removes the financial incentive to use a more expensive separately payable biological and promotes biosimilar use as a lower cost alternative to higher cost reference products.

Payment rates for drugs and biologicals (including biosimilars) under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on. Additionally, section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment (88 FR 81783). These payment rates are published in the quarterly release of Addendum B or ASP pricing files.

c. Invoice Drug Pricing for CY 2027

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94243 to 94244), we finalized that, for separately payable drugs or biologicals for which CMS does not provide a payment rate in Addendum B, which would indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and arithmetic mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, the MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. We generally expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under section 1847A of the Act. For drug products that are not required to report ASP under section 1847A of the Act (for example, radiopharmaceuticals), invoice pricing may be used on a longer-term basis until an arithmetic mean unit cost (MUC) can be calculated. We finalized the invoice pricing policy for drugs to be effective January 1, 2026, with the intent to make technical updates to outpatient hospital claims and to allow providers time to prepare for any operational changes. We noted that the National Uniform Billing Committee (NUBC) created a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals, effective January 2026 for the purpose of this policy. The NUBC value code created is 92 (Drug/Biologic Invoice Cost), with the definition of: ''Invoice Cost of drug/biologic. For use with Revenue Category 0636 when required by federal regulation.'' In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical clarification to this policy and clarified that CMS will determine whether the drug is not policy packaged; however, the MAC will continue to determine whether the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above

threshold packaging amount, as applicable (90 FR 53704). We reiterate that the drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. We acknowledge any rebates, chargebacks, or post-sale concessions may not be immediately available after treatment but hospital providers have 12 months from date of service to submit claims for payment and allowing providers to adjust submitted claims when the price concession is available.

For CY 2027, we are not proposing any additional changes to our invoice pricing policy for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We propose to continue our payment policy if CMS does not have pricing information (specifically, that ASP, WAC, AWP, and arithmetic mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices.

3. Payment Policy for Radiopharmaceuticals

For a complete history of the OPPS payment policy for radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

a. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, this payment policy for therapeutic radiopharmaceuticals will continue to apply in CY 2027.

Specifically, our policy of paying for separately payable pass-through therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals described in section V.A.1. of this proposed rule will continue to apply for CY 2027. We will pay for separately payable nonpass-through therapeutic radiopharmaceuticals through a modified ASP methodology where we pay at ASP plus 6 percent if ASP data are available. However, if ASP information is unavailable for a separately payable nonpass-through therapeutic radiopharmaceutical, we will continue to base the payment rate on arithmetic mean unit cost data derived from hospital claims. Our policy not to use WAC or AWP to establish payment for separately payable nonpass-through therapeutic radiopharmaceuticals if ASP is not available will continue for CY 2027. We explained our rationale in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) when we first adopted our policy to apply the principles of separately payable drug pricing to therapeutic radiopharmaceuticals.

For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We will rely on CY 2025 arithmetic mean unit cost data derived from hospital claims data for payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals for which ASP data are unavailable and update the payment rates for these products according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information becomes available.

The CY 2027 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).[68]

b. Payment Policy for Diagnostic Radiopharmaceuticals Without Claims Data

For CY 2025, we finalized, as described in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), to pay separately at arithmetic mean unit cost for diagnostic radiopharmaceuticals with a per day cost above our diagnostic radiopharmaceutical packaging threshold (proposed at $665 for CY 2027). We also finalized our policy to pay for pass-through diagnostic radiopharmaceuticals based on ASP, WAC, and AWP.

We continue to believe that paying for nonpass-through diagnostic radiopharmaceuticals using the arithmetic mean unit cost would appropriately pay for the average price of a nonpass-through separately payable diagnostic radiopharmaceutical, as discussed in section II.A.3.c. of this proposed rule. In our view, the arithmetic MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for radiopharmaceuticals because these pricing methodologies do not include discounts. Specifically, the absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we finalized to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status or claims data on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. To further clarify, these products will be paid based on ASP plus 6 percent, and at WAC plus 3 or 6 percent according to the policy in section V.B.2.a. of this proposed rule if ASP data are not available.

If the WAC also is unavailable, we proposed to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would be appropriate to use ASP, WAC, or AWP until an arithmetic MUC is established for new diagnostic radiopharmaceuticals with HCPCS codes that do not have passthrough status or claims data.

Please refer to section II.A.3.c. of this proposed rule for information regarding our broader payment policies for diagnostic radiopharmaceuticals, including our policy to pay for separately payable diagnostic radiopharmaceuticals with claims data based on the arithmetic mean unit cost data derived from hospital claims, and a list of the proposed qualifying diagnostic radiopharmaceuticals with per day costs exceeding the $665 threshold for CY 2027 in Table 4 of this proposed rule. The proposed CY 2027 payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).

[68] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

4. Proposed Payment for Blood Clotting Factors

For CY 2027, we propose to continue our established policy to provide payment for blood clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPS and to continue to pay a furnishing fee, authorized under section 1842(o)(5) of the Act. For a full discussion of our established payment policy for blood clotting factors, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71969 through 71970). In accordance with our policy as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we will announce the actual figure of the percent change in the CPI for medical care for the 12-month period ending with June of the previous year. The updated CY 2027 furnishing fee calculation based on that figure through the applicable program instructions will be posted on the CMS website at *https://www.cms.gov/medicare/payment/part-b-drugs/asp-billing-resources.*

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2027, this policy will continue to apply. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our policy, because we have no claims data and must determine if these products, drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals, exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the payment rate for the product, typically the ASP methodology, to determine whether their payment will be packaged as well as their payment status indicators.

6. CY 2027 Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals (hereinafter referred to collectively as ''drugs'' in this section) under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data are not available, the payment amount is the average price for the drug in a year established under sections 1842(o), 1847A, or 1847B of the Act, as the case may be. Payment rates for drugs have usually been established under section 1847A of the Act, which generally sets a default rate of the average sales price (ASP) plus 6 percent. Section 1833(t)(14)(A)(iii)(II) of the Act also provides that the average price for the drug in the year as established under section 1847A of the Act, is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), CMS reexamined the appropriateness of paying the ASP plus 6 percent for drugs acquired through the 340B Drug Pricing Program (hereinafter referred to as the ''340B Program''), a Health Resources and Services Administration (HRSA)-administered program that allows covered entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers. Based on findings of the Government Accountability Office (GAO),[69] the HHS Office of the Inspector General (OIG),[70] and the Medicare Payment Advisory Commission (MedPAC) [71] that 340B hospitals were acquiring drugs at a significant discount under the 340B Program, CMS adopted a policy beginning in 2018 generally to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. This adjustment amount was based on our concurrence at the time with an analysis by MedPAC that concluded that the estimated average minimum discount of 22.5 percent of ASP adequately represented the average minimum discount that a 340B participating hospital received for separately payable drugs under the OPPS (82 FR 59354 through 59371). Our intent in implementing this payment reduction was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340B drugs. We stated our belief that such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnished drugs to Medicare beneficiaries that were purchased under the 340B Program (82 FR 59353 through 59371).

b. Payment for 340B Drugs and Biologicals in CYs 2018 Through 2022

From January 1, 2018 through September 27, 2022, under the OPPS we generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5 percent. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal to adjust the payment rate for separately payable drugs (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. For ease of reference, the OPPS 340B drug payment adjustment policy is hereinafter referred to as the ''340B Payment Policy'' and refers both to the adjustments made to payment rates for 340B-acquired drugs described here and the corresponding rate adjustment for non-drug services and items described later in section V.B.6.c. of this proposed rule. We note that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals were exempted from the adjustments made to payment rates for 340B-acquired drugs primarily due to these hospitals receiving special payment adjustments under the OPPS. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change did not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which were excluded from the 340B Program. We also noted that

[69] Government Accountability Office. ''Medicare Part B Drugs: ''Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[70] Office of Inspector General. ''Part B Payment for 340B Purchased Drugs. OEI–12–14–00030''. November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[71] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

critical access hospitals are not paid under the OPPS and therefore were not subject to the OPPS 340B drug payment adjustment policy. Finally, in CY 2018, we did not initially apply the 340B Payment Policy to 340B-acquired drugs furnished in non-excepted off-campus provider-based departments (PBDs).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and made a series of refinements to the 340B Payment Policy, including a policy to pay for non-pass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than minus 22.5 percent of the reference biological product's ASP. Additionally, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy for CY 2019 and subsequent years.

During the CY 2019 OPPS/ASC rulemaking cycle, we also clarified that the 340B payment adjustment applied to drugs priced using either wholesale acquisition cost (WAC) or average wholesale price (AWP), and since the policy was first adopted, we applied the 340B payment adjustment to 340B-acquired drugs priced using these pricing methodologies. We made this clarification because inquiries from interested parties following the finalization of the 340B Payment Policy in 2018 demonstrated that there was confusion as to whether drugs receiving WAC or AWP pricing were subject to the 340B payment adjustment (83 FR 33632). WAC is the drug manufacturer's list price for wholesalers or direct purchasers in the U.S., not including prompt payment or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug pricing data. AWP is set using industry-recognized AWP reference sources.[72] The 340B payment adjustment for WAC-priced drugs was WAC minus 22.5 percent. 340B-acquired drugs that were priced using AWP were paid an adjusted amount of 69.46 percent of AWP (83 FR 37125).[73]

As discussed further in section V.B.6.f. of this proposed rule, the results of this policy meant that hospitals received an estimated $10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B Payment Policy not been implemented (88 FR 77162). These reduced payments are detailed in Table 47 and are derived from Addendum AAA[74] published with the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 final rule with comment period (hereinafter referred to as the ''Final Remedy rule'') (88 FR 77150).

TABLE 47: APPROXIMATE IMPACT IN REDUCED OPPS PAYMENT FOR 340B-ACQUIRED DRUGS 2018 THROUGH 2022

	2018	2019	2020	2021	2022
Approximate Reduced OPPS Drug Payment (including beneficiary cost sharing) (billions)	$1.9	$2.2	$2.3	$2.4	$1.8*
*Amount January 1 to September 27, 2022. Reduced payments under the 340B Payment Policy were not in effect after September 27, 2022.					

For more detailed descriptions of our OPPS payment policy for drugs acquired under the 340B Program during this timeframe, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); the CY 2023 OPPS/ASC final rule with comment period (87 FR 71972 through 71973); the CY 2024 OPPS/ASC final rule with comment period 88 FR 81789 through 81792; and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53707 through 53722).

c. Payment for Non-Drug Items and Services in CY 2018 Through CY 2022

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216, 59258), to comply with the statutory budget neutrality requirements under sections 1833(t)(9)(B) and (t)(14)(H) of the Act, we finalized our proposal to redistribute our original, estimated reduction in payments for separately payable drugs as a result of the 340B Payment Policy by increasing the conversion factor used to determine the payment amounts for non-drug items and services. As further described in the CY 2018 OPPS/ASC final rule with comment period, we used updated CY 2016 claims data and a list of 340B-eligible providers to calculate an estimated impact of $1.6 billion based on the final CY 2018 policy to pay for OPPS 340B-acquired drugs at a payment rate of generally ASP minus 22.5 percent. To effectuate the budget

[72] *www.cms.gov/files/document/part-b-drug-payment-limits-overview.pdf.*

[73] The 69.46 percent of AWP was calculated by first dividing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which was similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

[74] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1793-f.*

neutrality provisions of the OPPS for CY 2018, we redistributed an estimated $1.6 billion in reduced drug payments from adoption of the final 340B payment methodology to all hospitals paid under the OPPS by increasing the payment rates by 3.19 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018. We carried through this conversion factor adjustment from CYs 2019 through 2022, increasing payments for non-drug items and services in these CYs. This resulted in approximately $7.769 billion, which for ease of reference in this proposed rule we hereafter refer to as $7.8 billion, in additional spending on non-drug items and services from CYs 2018 through 2022.

d. Litigation History of the 340B Payment Policy

The 340B Payment Policy was the subject of significant litigation. See the Proposed Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (hereinafter referred to as the ''proposed remedy rule'') for a more comprehensive summary of the litigation history (88 FR 44079 through 44080).

On June 15, 2022, the Supreme Court held that because HHS had not previously conducted a survey of hospitals' acquisition costs, we could not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass'n* v. *Becerra,* 596 U.S. 724, 739 (2022). The Supreme Court declined to opine on the appropriate remedy, *see id.,* and on September 28, 2022, the district court vacated the prospective portion of the CY 2022 reimbursement rate for 340B-acquired drugs, *see Am. Hosp. Ass'n* v. *Becerra,* No. 1:18–cv–2084–RC, 2022 WL 4534617, at *5 (D.D.C.).[75] On January 10, 2023, the district court remanded without vacatur to give the agency the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for CY 2018 through CY 2022. *See Am. Hosp. Ass'n* v. *Becerra,* No. 1:18–cv–2084–RC, 2023 WL 143337, at *6 (D.D.C.).[76]

e. Payment for 340B-Acquired Drug Claims for September 28, 2022 Through CY 2026

The agency complied with the district court's September 28, 2022 decision by uploading revised OPPS drug files to pay the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970), we finalized a policy reversing the 340B Payment Policy so that going forward we would pay for 340B-acquired drugs no differently than we pay for drugs that are not acquired through the 340B Program. To do so, we first provided that drugs acquired through the 340B Program would be paid at the statutory default rate (generally ASP plus 6 percent) for CY 2023. Second, to ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, we finalized a reduction of 3.09 percent to the 2023 OPPS conversion factor. This one-time adjustment to the conversion factor removed the effect of this aspect of the 340B Payment Policy, as originally adopted in CY 2018, for CY 2023 and subsequent years. This adjustment reduced the conversion factor to the conversion factor that would have been in place in CY 2023 if the 340B Payment Policy had never been implemented. For more detail on the payment rate for drugs acquired under the 340B Program for CY 2023 and the corresponding adjustment to the conversion factor to maintain budget neutrality as a result of reversing the 340B adjustment and paying for all separately payable drugs at ASP plus 6 percent (or WAC plus 3 or 6 percent or 95 percent of AWP), we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71973 through 71976).

For CYs 2024 through 2026, consistent with our policy finalized for CY 2023, we continued to pay the statutory default rate for 340B-acquired drugs (88 FR 81789 through 81791).

f. Remedy Payment Adjustment for 340B-Acquired Drugs From CY 2018 Through September 27, 2022

The agency complied with the district court's January 10, 2023, remand order by issuing the Final Remedy rule on November 8, 2023 (88 FR 81540). The purpose of this rule was to address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPPS.

To address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022, CMS made one-time lump sum payments to affected 340B covered entity hospitals, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs from CY 2018 through September 27, 2022 and what they would have received for those drugs if the 340B adjustment had not been in place. These one-time lump sum payments were issued in early 2024. For more information on the calculation and distribution of the one-time lump sum payments, see the Final Remedy rule (88 FR 77156 through 77170).

g. Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022

As we described under section I.A.3. of the Final Remedy rule (88 FR 77151), to comply with statutory budget neutrality requirements, the decreased payments made to 340B hospitals for drugs in CY 2018 through September 27, 2022, were budget neutralized by corresponding increased payments to all hospitals for non-drug items and services starting in CY 2018 through CY 2022. When the past payments for these drugs were subsequently increased through the one-time lump sum payments in 2024, the same budget neutrality requirements obligated us to decrease the non-drug item and services payments made from CY 2018 through CY 2022.

To reduce the burden on providers of immediately offsetting the estimated $7.8 billion of increased non-drug item and services payments made from CY 2018 through CY 2022, we finalized a policy to implement the offset prospectively over the course of several years. As we explained in the Final Remedy rule (88 FR 77172), this approach was similar to the original budget neutrality adjustment in the 340B Payment Policy that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the downward adjustment in the payment rate for drugs acquired under the 340B Program. We finalized in the Final Remedy rule that, beginning in CY 2026, we would reduce the conversion factor for non-drug items and services to all OPPS providers—except any hospital that enrolled in Medicare after January 1, 2018 (as described further below)—by 0.5 percent each year until the total offset was reached (which we estimated would take approximately 16 years (88 FR 77181)).

As we stated in the Final Remedy rule, we believed an annual reduction in the conversion factor was appropriate because it balanced the need to address the past payments for non-drug items

[75] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.*

[76] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.*

and services to ensure budget neutrality while also ensuring that the offset was not immediately financially burdensome on impacted entities, which we believed would be the case if we were to apply an adjustment for the full offset amount in a single year (88 FR 77170).

Accordingly, the Final Remedy rule finalized changes to the calculation of the OPPS conversion factor applicable to non-drug items and services beginning in CY 2026. Specifically, we codified a 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services in the regulations as codified at § 419.32 (b)(1)(iv)(B)(*12*). As currently implemented, this 0.5 percent reduction remains in effect until the estimated payment reduction reaches $7.8 billion, which we estimated will occur in CY 2041. For a full discussion of the CY 2026 adjustment to the conversion factor for non-drug items and services, see the Final Remedy rule (88 FR 77156 through 77170).

In finalizing our policy to apply a prospective adjustment, we recognized that any hospital that enrolled in Medicare after January 1, 2018 (hereinafter referred to as a ''new provider'') received less than the full amount of the increased non-drug item and service payments made during that time than they otherwise would have received if enrolled prior to that date (88 FR 44080). We therefore exempted these providers from the prospective rate reduction, which was predominantly designed to account for non-drug item and service payments made during CY 2018 through CY 2022. As we explained, that means we calculate payment rates for new providers using the conversion factor before applying the 0.5 percent annual reduction to the conversion factor for non-drug items and services that apply to hospitals that are not ''new providers'' for purposes of this policy. For the purpose of designating a new provider, we define the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. We codified the exclusion of these new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32.

The providers that were determined to be subject to the payment reduction based on our review of provider enrollment and OPPS billing records were listed in Addendum R–340B Remedy Offset Providers to the CY 2026 OPPS/ASC final rule with comment period. We indicated in the CY 2026 OPPS/ASC final rule with comment period that providers not included on this list (providers that began billing Medicare under the OPPS after January 1, 2018) would not be subject to the payment reduction. For a complete discussion of our exclusion of new providers from the prospective payment adjustment, we refer readers to the Final Remedy rule (88 FR 77182 through 77185) and the CY 2026 final OPPS/ASC rule with comment period (90 FR 53709 through 53710).

h. CY 2026 Prospective Payment Adjustment

In the CY 2026 OPPS/ASC proposed rule, we proposed to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for non-drug items and services from 0.5 to 2 percent effective January 1, 2026 (90 33634). Under this revised rate, we expected it would take approximately 6 years to reach the total offset of $7.8 billion. As we explained in the CY 2026 OPPS/ASC proposed rule, while we continued to believe that a reduction to the OPPS conversion factor was the best way to effectuate budget neutrality, we questioned whether a 0.5 percentage point annual reduction for approximately 16 years best achieved the goal of the Final Remedy rule, which was to restore hospitals to as close to the financial position they would have been in had the 340B Payment Policy never been implemented as is reasonably feasible. Specifically, we noted that the further away from CY 2018 through CY 2022 the conversion factor adjustments extend, the less likely it is that hospitals' relative utilization patterns of non-drug items and services would align with the relative utilization patterns of non-drug items and services from CY 2018 through CY 2022.

Because applying an annual reduction to the conversion factor for all non-drug items and services does not directly identify and recoup the specific amount owed by each hospital, but rather seeks to recoup the aggregate increased payments made to all hospitals for non-drug items and services starting in CY 2018 through CY 2022, it is important to apply the annual reduction to the OPPS conversion factor to the payment for non-drug items and services furnished during calendar years in which hospitals' utilization patterns for such non-drug items and services most closely resemble their utilization patterns during CYs 2018 through 2022. Doing so helps to ensure that each hospital repays an amount that best approximates the excess payments it received under the 340B Payment Policy.

We explained in the CY 2026 OPPS/ASC proposed rule (90 FR 53710) that a hospital's utilization of non-drug items and services would likely diverge more from CY 2018 utilization in CY 2041 than it would in CY 2031 or CY 2026. The longer the recovery timeframe, the more each hospital's utilization of non-drug items and services will likely diverge from what the hospital's utilization of non-drug items and services was during the 2018–2022 timeframe the 340B Payment Policy was in place. Consequently, under the current recovery timeframe, the cumulative reduction applied to each hospital is less likely to reflect the amount of payment the hospital received for increased non-drug services from 2018 through 2022. As a result, it is less likely that each hospital will be restored to the financial position it would have occupied had the 340B Payment Policy in effect from 2018 to 2022 not been implemented.

Another factor that caused us to question the appropriateness of a 16 year recovery timeframe was the fact that by beginning the decrease to non-drug item and service payments in CY 2026, there was already an 8-year delay between the first year of the OPPS 340B Payment Policy and the first year of the prospective offset. (90 FR 53710). Thus, we observed, the longer it takes for us to fully recover the $7.8 billion, the less suited the relative burden on hospitals from the adjustments would be to the relevant benefits those hospitals previously received. We also recognized the possibility that at least some hospitals that benefited from the increased payments from CY 2018 through CY 2022 would leave the market before 2041, increasing the risk that the remaining hospitals might ultimately account for a larger share of the payment reductions than they would have if the annual reduction to the OPPS conversion factor concluded sooner. We additionally noted that the $7.8 billion dollar figure calculated in the Final Remedy rule (88 FR 77150) does not, and will not, account for inflation and does not contain interest even though the prospective offset is occurring many years after both the start of the 340B Payment Policy in CY 2018 as well as the lump sum remedy payments made in CY 2024.

We acknowledged in the CY 2026 OPPS/ASC proposed rule (90 FR 33635) that revising the annual reduction from 0.5 percent to 2 percent would be a change to the approach we finalized in the Final Remedy rule and that, at the time of the Final Remedy rule, we

considered but did not adopt a suggestion from a commenter requesting that we recover the amount over a shorter timeframe than 16 years. (88 FR 77179.) We indicated that our basis for not accepting the suggestion in the Final Remedy rule was that the 0.5 percent rate/16-year timeframe ''properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities'' (90 FR 33635). We stated in the CY 2026 OPPS/ASC proposed rule that this balancing insufficiently accounted for the main premise of the Final Remedy rule, which is to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. We explained that, for the reasons described above, we believed that a 6-year time frame better achieved that main goal and better balanced that goal and our budget neutrality obligations against hospital burden and reliance interests. We noted that the 16-year timeframe was more than three times longer than the 5-year period the 340B Payment Policy was in place. The 6 years we expected that the revised policy would be in effect, by contrast, would be closer to the timeframe the 340B Payment Policy was in place, and that a 2 percent payment reduction was still well below the 3.19 percent payment increase hospitals received for that time period (82 FR 52624 through 52625). We also indicated that because we proposed this policy in advance of CY 2026 and before any rate reductions went into effect for OPPS and Medicare Fee for Service payments, any reliance interests hospitals had in a policy that had not been implemented yet for these payment systems would be minimal and outweighed by the other considerations discussed in the CY 2026 OPPS/ASC proposed rule (90 FR 33635).

We did not finalize our proposal to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) in the CY 2026 OPPS/ASC final rule and the 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services finalized in the Final Remedy rule went into effect on January 1, 2026. The decision not to finalize an increased reduction for CY 2026 was made in response to concerns brought forth by some commenters. Specifically, we said ''[w]hile we disagree with many of the arguments these commenters raise, we are persuaded by the commenters to the extent that we will not finalize in CY 2026 our proposal to increase to 2 percent the 0.5 percent adjustment in 42 CFR 419.32(b)(1)(iv)(B)(*12*). We currently anticipate delaying a change for just 1 year. Thus, while we will retain the original 0.5 percent adjustment in the conversion factor in CY 2026, hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027 . . . .—We do so based on the unique circumstances here.'' (90 FR 53714).

i. CY 2027 Proposed Prospective Payment Adjustment

Effective January 1, 2027, we propose to increase the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for non-drug items and services from 0.5 percent to 3 percent. Specifically, we propose to revise § 419.32(b)(1)(iv)(B)(*12*) to limit the 0.5 percent reduction to CY 2026 and add a new paragraph (*13*) implementing an annual 3.0 percent reduction (excluding new providers with a CMS certification number (CCN) effective date of January 2, 2018, or later) starting in CY 2027 and continuing until the estimated payment reductions made in accordance with paragraphs (*12*) and (*13*) for all applicable hospital outpatient items and service reaches $7.769 billion. Under this revised rate, we expect we will reach this total by the end of CY 2029 (see Table 48). We recognize that this proposed annual reduction is greater than the 2 percent annual reduction we originally proposed for CY 2026. As further discussed below, we considered the following in establishing this proposal:

First, a 3 percent reduction is necessary to achieve the outcome for which we originally proposed the 2 percent annual reduction in CY 2026. That is, to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. By recovering the funds during a timeframe that aligns with the period in which the funds were originally paid out and applying the reduction in calendar years for which a hospital's utilization of non-drug items and services is more likely to align with its utilization during the period when the 340B Payment Policy was in effect, CMS will better ensure that the reduction in payments to each hospital approximates the amount by which that hospital was overpaid. A total recoupment timeframe of roughly 6 years after the 340B remedy payments were made in CY 2024 more closely aligns with the 5 year timeframe the 340B Payment Policy was in place, as compared to the 8 years from CY 2024 that we estimate a 2 percent recoupment would require (see Table 48). Based on our analysis, we believe that, as additional time elapses following the period during which the 340B Payment Policy was in effect, hospitals' utilization of non-drug items and services is increasingly likely to diverge from their utilization patterns during that period. Since CMS is recouping the increased payments made for nondrug items and services while the 340B Payment Policy was effective by applying a reduced conversion factor to nondrug items and services furnished during the calendar years following the 340B Payment Policy's end date, the farther out these reductions apply, the less likely it is that the total recoupment for each hospital will align with the amount each hospital was overpaid. For example, if a hospital's utilization rate of non-drug items and services is three times greater in 2030 than it was in 2020, then a reduced conversion factor applied to the items and services furnished in 2030 could result in CMS recouping more than what the hospital was initially paid in 2020. Consequently, it is less likely that the hospital would be restored to the financial position they would have been in had the 340B Payment Policy never been in effect. A total recoupment timeframe of 6 years would recover the funds in a manner that limits this divergence in utilization while avoiding the burden on providers that would result from a shorter recovery timeframe.

Second, a 3 percent payment reduction is the most logical and appropriate percentage to apply as it closely approximates the 3.19 percent payment increase hospitals received for non-drug items and services from CYs 2018 through 2022 to budget neutralize the reduced drug payments resulting from the 340B Payment Policy. This approach is also consistent with the approach we adopted in CY 2023 (87 FR 71975) to maintain budget neutrality when we returned to our policy of paying ASP plus 6 percent for 340B acquired drugs.

With respect to implementing a 3 percent reduction in CY 2027 versus delaying implementation until a later CY to provide hospitals with additional time to prepare, we determined that implementing this payment reduction

starting CY 2027 would be appropriate. We have repeatedly emphasized that shorter recoupment windows would be considered and/or proposed in CY 2027. In the CY 2026/ASC final rule with comment period, we expressly stated ''hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027'' (90 FR 53714). Elsewhere in that rule we stated that ''we anticipate implementing a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) in next year's rulemaking'' (90 FR 53718). We communicated this same message in the Medicare Fact Sheets and Press Releases for the CY 2026 OPPS/ASC final rule with comment period to ensure that hospitals were aware of the likely increase in the offset percentage in CY 2027.[77] Because hospitals have been aware that we would likely propose an increased payment reduction in CY 2027 rulemaking, we do not believe hospitals need additional time to prepare for this repayment schedule.

We seek comment on our proposal to increase the annual percent reduction to 3 percent. We also specifically seek comment on the advisability of increasing the annual percent reduction to 2 percent.

TABLE 48: ILLUSTRATION OF THE PROPOSED 3 PERCENT AND ALTERNATIVE 2 PERCENT CONVERSION FACTOR ANNUAL REDUCTION TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2027 TO MAINTAIN BUDGET NEUTRALITY IN THE CY 2027 OPPS/ASC PROPOSED RULE

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	Remedy Payments Made in Q1 of CY 2024	No Remedy Offset Applied	67.5	77.0	83.6	90.6	97.7	105.1
			Alternative 2 Percent Payment Reduction					
Amount (millions)			300	1,500	1,700	1,800	2,000	500*
Estimated Total Cumulative Offset (millions)			300	1,800	3,500	5,300	7,300	7,769
			Proposed 3 Percent Payment Reduction					
Amount (millions)			300	2,300	2,500	2,700*		
Estimated Total Cumulative Offset (millions)			300	2,600	5,100	7,769		

* Note, the final year's offset is estimated to be less than 2 or 3 percent in order to meet the total estimated offset of $7.769 billion. The amounts illustrated in Table 48 reflect the total amount of reduced spending, which includes both Medicare and Beneficiary cost-sharing. Note, the figures in the table are rounded, which may create some display discrepancies, but all figures are calculated with the final recoupment amount being $7.769 billion.

7. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

a. Background

In the CY 2000 OPPS final rule (65 FR 18434), CMS implemented the PPS for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In the CY 2000 OPPS final rule, we noted that the OPPS applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as ''outpatient services provided by hospitals of the Indian Health Service (IHS).'' We stated that these services would ''continue to be paid under separately established rates which are published annually in the **Federal Register**'' and, in the CY 2002 OPPS/ASC final rule (66 FR 59856), we finalized a revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4), which specifies that hospitals of the IHS are excluded from the OPPS.

In the intervening years, IHS and tribal facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates.[78] Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2026, the Medicare Outpatient per visit rate is $733 for the lower 48 States (hereinafter referred to as ''the lower 48 AIR'') and $1,233 for Alaska.[79]

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280

[77] *https://www.cms.gov/newsroom/fact-sheets/calendar-year-2026-hospital-outpatient-prospective-payment-system-opps-ambulatory-surgical-center.*

[78] *https://www.ihs.gov/BusinessOffice/reimbursement-rates/.*

[79] 91 FR 2787 (January 22, 2026); *https://www.federalregister.gov/documents/2026/01/22/2026-01178/reimbursement-rates-for-calendar-year-2026.*

through 94286), we finalized a policy to separately pay IHS and tribal hospitals for high-cost drugs, biologicals, and radiopharmaceuticals (hereinafter referred to as ''drugs'' for the purpose of this section) furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the AIR is calculated.[80] We finalized a continuation of this policy, without modification, in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53722 through 53723). We note that the AIR and the add-on payment are paid out of the Part B trust fund and are not subject to OPPS budget neutrality.

We defined high cost drugs (that is, drugs qualifying for the add-on payment) for the purpose of the policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS whose per day cost exceeds two times the lower 48 AIR amount in effect at the time of the release of each year's OPPS/ASC final rule with comment period. In the CY 2026 OPPS/ASC final rule with comment period, this amount was identified as $1,436 (2 times the CY 2025 lower 48 AIR of $718).

To determine the calculated per day cost for each drug HCPCS code, we employed a methodology similar to our longstanding methodology used to calculate the per day cost of drugs for OPPS payment purposes. Specifically, to calculate the per day cost for CY 2026, we used an estimated payment rate based on the ASP methodology payment rate, which for purposes of the policy was generally ASP plus 0 percent (which is the payment rate for separately payable IHS drugs under the policy). We then used the manufacturer-submitted ASP data from the fourth quarter of CY 2024 to determine the per day cost. For drugs that did not have either an ASP-based payment rate or a payment rate based on WAC, we used arithmetic MUC of the items derived from the CY 2024 hospital claims data to determine their per day cost. For HCPCS codes for drugs that were proposed for separate payment in the CY 2026 OPPS/ASC proposed rule with comment period but then had per day costs equal to or less than $1,436 (2 times $718) in the CY 2026 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2026 OPPS/ASC final rule with comment period, those drugs received separate payment in CY 2026.

We finalized that the amount of the add-on payment for a high-cost drug would be the ASP for the drug with no additional payment (that is, ASP plus 0 percent). We note that this add-on payment was implemented on a per-dose basis. In the event ASP pricing information was not available for a particular drug, we paid the WAC plus 0 percent and if WAC pricing information was not available, we paid 89.6 percent of AWP. If AWP was not available, we paid the arithmetic MUC. We also adopted a drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

To implement this policy, we finalized in the CY 2025 OPPS/ASC final rule with comment period a recurring annual process in which the lower 48 AIR in effect at the time of the release of each year's OPPS/ASC final rule with comment period would be used to create a list of drugs qualifying for the add-on payment for the following calendar year. Once the drugs qualifying for the add-on payment were determined, the payment rate for a unit of the drug would be determined in accordance with the above described pricing hierarchy. The results of that process for CY 2025 were displayed in Addendum Q to the CY 2025 OPPS/ASC final rule with comment period. We additionally finalized that during the calendar year, the list of drugs would be modified on a quarterly basis (January, April, July, October) to add new-to-market drugs with per-day costs that exceeded two times the lower 48 AIR and to update qualifying drugs' ASPs.

We finalized a continuation of this annual process, without modification, in the CY 2026 OPPS/ASC final rule and the results of that process for CY 2026 were displayed in Addendum Q to the CY 2026 OPPS/ASC final rule. For a full discussion of the AIR add-on payment policy for high cost drugs provided by IHS and tribal hospitals, we refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280 through 94286) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53722 through 53723).

b. AIR Add-On Payment for High-Cost Drugs Provided by IHS and Tribal Facilities Policy for CY 2027

For CY 2027, we propose to continue the policy as described in the CY 2025 and CY 2026 OPPS/ASC final rules.

Consequently, for CY 2027, we propose to continue to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authorities under which the AIR is calculated.

We propose to continue to define high cost drugs (that is, drugs qualifying for the add-on payment) for the purpose of the policy as any drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS which have per day costs exceeding two times the lower 48 AIR amount in effect at the time of the release of the CY 2027 OPPS/ASC final rule with comment period. For CY 2027, we propose that if the CY 2026 lower 48 AIR amount is in effect at the time of the release of the CY 2027 OPPS/ASC final rule with comment period, this amount would be $1,466 (2 times the CY 2026 lower 48 AIR of $733).

To determine the calculated per day cost for each drug HCPCS code, we propose to continue using an estimated payment rate based on the ASP methodology payment rate (generally ASP plus 0 percent) and then using the manufacturer-submitted ASP data from the fourth quarter of CY 2025 to determine the per day cost. For drugs that do not have either an ASP-based payment rate or a payment rate based on WAC, we propose to continue to use the arithmetic MUC of the items derived from the CY 2025 hospital claims data to determine their per day cost.

We propose that the amount of the add-on payment for each dose of a high-cost drug would continue to be the ASP for the drug with no additional payment (that is, ASP plus 0 percent). In the event ASP pricing information is not available for a particular drug, we propose to continue to pay the wholesale acquisition cost (WAC) plus 0 percent. If WAC pricing information is not available, we propose to continue to pay 89.6 percent of AWP. If AWP pricing information is not available, we propose to continue to pay the arithmetic MUC. Finally, we propose to continue the drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

c. Proposed List of Drugs Qualifying for the Add-on Payment for CY 2027

Using two times the lower 48 AIR amount of $733 that is in effect for CY 2026 and applying the above described per-day cost methodology and pricing

[80] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

hierarchy, we have included as proposed Addendum Q a preliminary list of the drugs that would qualify for the proposed add-on payment and their proposed add on payment rates for CY 2027.

We propose to create a final Addendum Q in the CY 2027 OPPS/ASC final rule with comment period using the claims data (units used per day) and ASPs, or pricing hierarchy, available at that time. We also propose that for HCPCS codes for drugs that are proposed for separate payment in CY 2027, but then have per day costs equal to or less than $1,466 (2 times $733) in the CY 2027 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2027 OPPS/ASC final rule with comment period, those drugs would still receive separate payment in CY 2027.

Finally, as we did in CY 2025 and CY 2026, we propose to modify the list on a quarterly basis (January, April, July, October) to add new-to-market drugs with per-day costs that exceed two times the lower 48 AIR and to update qualifying drugs' ASPs.

8. Medicare OPPS Drugs Acquisition Cost Survey

a. Background

(1) Publication of Notice of Intent To Conduct Medicare OPPS Drugs Acquisition Cost Survey

Section 1833(t)(14)(A)(iii) of the Act requires the Secretary to set payment rates for specified covered outpatient drugs (SCODs) [81] beginning in 2006 at the amount the Secretary determines to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available. To collect the cost survey data for the Secretary to use for 2006 payment rates, section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the U.S. to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD. To inform payment rates in later years, section 1833(t)(14)(D)(ii) of the Act requires the Secretary periodically to conduct surveys of hospital acquisition costs for each SCOD. In developing that survey, section 1833(t)(14)(D)(i)(II) of the Act requires the Secretary to take into account certain recommendations from the Comptroller General regarding frequency and methodology of subsequent surveys.

The GAO conducted the required surveys in 2004 and 2005, and, in reporting the results in 2006, recommended that the Secretary thereafter validate, ''on an occasional basis—possibly every 5 or 10 years—ASP data that manufacturers report to CMS for developing SCOD payment rates''.[82] As noted in the CY 2026 OPPS/ASC proposed rule (90 FR 33653), in the years following the GAO's recommendation, CMS had not yet conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, ''Lowering Drug Prices by Once Again Putting Americans First.'' [83] Section 5 of the E.O., ''Appropriately Accounting for Acquisition Costs of Drugs in Medicare,'' directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the acquisition costs for SCODs at hospital outpatient departments.

Accordingly, in the CY 2026 OPPS/ASC proposed rule (90 FR 33653), we announced that under section 1833(t)(14)(D)(ii) of the Act we would be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs. We indicated that we intended for the survey to open starting at the end of CY 2025 to early CY 2026. We also stated that we had reviewed and taken into account the Comptroller General's recommendations regarding the frequency and methodology of these surveys in developing our proposed survey, and that we intended for the survey to be completed in time for the survey results to be used to inform policy making beginning with the CY 2027 OPPS/ASC proposed rule. We indicated that we intended to propose and seek comment on any payment rates for SCODs based on the survey results in CY 2027 rulemaking.

In the CY 2026 OPPS/ASC final rule (90 FR 53754 through 53766 and 54049 through 54052), after responding to public comments, including those received through the proposed survey Paperwork Reduction Act (PRA) submission process, we finalized our proposal outlining our intent to conduct a required outpatient drug acquisition cost survey to all hospitals paid under the OPPS, pending final approval from OMB. OMB approval was granted on December 29, 2025 (OMB control number 0938–1487, expires August 31, 2028).[84]

(2) OPPS Drug Acquisition Cost Survey Design and Implementation

(a) Study Population

We identified approximately 4,500 entities for inclusion in the survey study population due to their submission of at least one qualifying Fee-For-Service claim under the OPPS during the survey study period (July 1, 2024 through June 30, 2025). Qualifying claims met all defined criteria: (1) claim date of service (July 1, 2024 and June 30, 2025), (2) claim type (Part B outpatient), (3) facility type code (12 [hospital inpatient/home heath], 13 [hospital outpatient], 14 [hospital other], and 76 [community mental health center]), (4) payment amount (greater than zero), and (5) status indicator denoting separately payable drugs or other relevant Part B outpatient services with status indicators (G, H, J1, J2, K, Q1, Q2, Q3, Q4, R, S, T, U, OR V). We removed all claims billed by hospital types that are not paid under the OPPS.[85] Finally, we ensured that each entity had valid Medicare enrollment during the survey study period using the Provider Enrollment, Chain, and Ownership System (PECOS). There was no sampling as all OPPS hospitals were invited to participate in the survey and provide the required data.

As described in the PRA approved by OMB, we expect to survey these hospitals every four (4) years. We believe that this frequency will appropriately balance the burden imposed on hospitals of completing the survey with ensuring that we capture the required data to inform payment rates as required under section 1833(t)(14)(D)(I)(ii) of the Act. However, this frequency is an intention and could be revised.

(b) Survey Scope and Design

The guiding principle in the design of the survey was to collect the data necessary to inform payment policy as required by statute in a manner that imposed the least amount of burden to the extent practicable on the hospitals providing the data. The survey collected acquisition cost data for separately

[81] For the definition of a SCOD, see section 1833(t)(14)(B) of the Act at *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

[82] *https://www.gao.gov/assets/gao-06-372.pdf.*

[83] *https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

[84] *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0938-014* and *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202512-0938-024.*

[85] As stated in 42 CFR 419.20(b), the following hospital types are not paid under the OPPS: critical access hospitals; Maryland waiver hospitals; hospitals located outside the 50 states, the District of Columbia, and Puerto Rico; Indian Health Service hospitals; and rural emergency hospitals. *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20.*

payable outpatient drugs at the 11-digit National Drug Code (NDC) level for 1,843 NDCs, which correspond to 519 drug HCPCS.[86] We note that more than one NDC may be associated with a given HCPCS code and vice versa. These NDCs were identified by analyzing the drugs and biologicals that were separately payable under the OPPS during the survey period of July 1, 2024 through June 30, 2025 and for which there was a payment made under the OPPS during that period. We excluded NDCs with either an expiration date or a marketing end date prior to July 1, 2024, using FDA national drug code and structured product labeling data elements (NSDE) data[87] because these drugs would no longer be available for purchase during the study survey period.[88]

(c) Acquisition Date Reporting and Data Elements

The survey captured acquisition data for drugs purchased between July 1, 2024 and June 30, 2025. This 12-month time period aligns with GAO's 12-month survey period for their original study of July 1, 2003 through June 30, 2004. This time period also provided a 6-month window between the end of the survey period and the start of the survey submission window to ensure adequate time for all rebates, discounts, and price concessions to be finalized, so they could be incorporated into the NDC acquisition cost submitted by hospitals.

The survey instructed hospitals to report 4 pieces of data for each NDC purchased during the 1-year survey period:

- Total Units Purchased—Non-340B
- Total Net Acquisition Cost—Non-340B
- Total Units Purchased—340B
- Total Net Acquisition Cost—340B

Net acquisition cost was defined as the total amount paid by the hospital inclusive of all discounts, rebates, and price concessions applicable at the NDC level.

This design reflected our recognition that certain discounts may apply depending on which provider furnished the drug and whether an eligible patient received the drug (for example, for drugs acquired through the 340B Program). Consequently, the survey asked hospitals to separately list their acquisition costs for drug NDCs acquired through the 340B Program and drug NDCs acquired outside of the 340B Program to ensure that all discounts were accurately captured and represented the hospital's acquisition costs.

(d) Treatment of Discounts and Price Concessions

The survey asked hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC. This included both discounts able to be directly applied to each individual NDC and those discounts that were not necessarily linked to a single NDC (*e.g.,* invoice-level discounts, wholesaler rebates, prompt pay discounts, and other financial concessions, or other discounts). Respondents were also asked to separately provide information about any non-NDC-specific discounts or rebates received as a result of membership in a Group Purchasing Organization (GPO) or other buying group.

(e) Data Collection Process

Data were collected through the CMS Fee-for-Service Data Collection System (FFSDCS) via the Medicare OPPS Drug Acquisition Cost Survey (hereinafter referred to as ''ODACS'') module. Hospitals first designated a Hospital Point of Contact (POC) and a Submitter responsible for data submission. Submitters then submitted data through (1) uploading of a standardized Excel (.xlsx) file; or (2) manual data entry through the FFSDCS via the ODACS module. Once the Submitter uploaded or entered the required data, they then officially submitted that data to CMS and attested to the validity, integrity, and completeness of the data being submitted.

(f) Data Validation and Quality Assurance

The FFSDCS ODACS module included automated validation checks to promote completeness, formatting accuracy, and logical consistency. For uploaded data, errors and missing information were flagged on the module upload page, accompanied by error explanations. For manually entered data, the module provided hover-over tips for data entry fields and was programmed to accept data only in specific formats. The system alerted users if data was formatted incorrectly. Submitters were able to correct and reupload data during the collection window prior to final attestation.

(g) Survey Window

The ODACS module opened on January 1, 2026 and closed on April 7, 2026. The original survey window was January 1, 2026 through March 31, 2026; however, after the survey window opened we extended the window for an additional week, through April 7, 2026, based on hospitals' request for additional time to respond. We believe that approximately 14 weeks was sufficient for hospitals to respond to the survey, particularly given the outreach and education that CMS engaged in prior to and during the survey window.

(h) Outreach and Education

We engaged in extensive outreach and education to hospitals in advance of the survey start date to ensure that respondents were aware of the survey and how to complete it. CMS began reaching out to hospitals using provider enrollment and other publicly available contact information in September 2025. Specifically, CMS identified a hospital POC from each hospital paid under the OPPS and reached out to them to make them aware of the survey and provide them with instructions on selecting a hospital representative (Submitter) to register with the CMS Identity Management System (IDM) to access the survey module and report the survey data. To walk respondents through this process, a step-by-step registration guide was issued by CMS in November 2025 and a data submission guide was provided on January 1, 2026.[89] These guides were posted to a new ODACS-specific web page[90] that was created by CMS to serve as a central hub for information and resources for hospitals. CMS also conducted two educational webinars[91] with hospitals in December 2025, which were recorded and posted to the ODACS web page. To ensure that respondents had the support they needed during the survey, CMS established a dedicated email address and helpline to provide technical assistance. To address frequently asked questions, CMS posted a FAQ document[92] to the ODACS web page and updated it during the survey to reflect additional questions asked by respondents via email and the helpline as the survey progressed. Finally, prior to and throughout the survey period,

[86] ODACS Acquisition Data Template: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.*

[87] *https://www.fda.gov/industry/structured-product-labeling-resources/nsde.*

[88] The expiration date is the expiration date of the last lot distributed. The marketing end date signifies that the drug is no longer actively manufactured or promoted, or the company has officially decided to stop commercializing it.

[89] *www.cms.gov/files/document/submitter-user-guide.pdf.*

[90] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.*

[91] *https://www.cms.gov/files/document/odacs-training-webinar.pdf.*

[92] *https://www.cms.gov/files/document/odacs-faq.pdf.*

CMS sent periodic communications to POCs to remind them of upcoming deadlines and resources available for assistance.

b. Data Analysis and Methodology

(1) Selection of a Methodology To Calculate Acquisition Cost Margins

In accordance with section 1833(t)(14)(D)(ii) of the Act, we took into account GAO's recommendations and analyzed the survey data to validate whether the manufacturers' reported drug ASP data appropriately and accurately reflects hospitals' drug acquisition costs. To do so, we compared hospitals' survey-reported acquisition costs for all survey-eligible drugs to the equivalent ASP-based Medicare payment amount for those drugs under the OPPS, less any drug-specific payment rate add-ons. This comparison was constructed as a percent difference between these two values, termed the acquisition cost margin.

We calculated this acquisition cost margin by first finding the difference between (1) the total acquisition costs reported for all NDCs in the survey and (2) the volume-weighted sum of their corresponding ASP payment rates, the latter of which was calculated by multiplying the survey reported units purchased for each NDC by its applicable ASP plus 0 rate.[93] We then divided that difference by the total ASP-based payment to find the percent margin between acquisition costs and ASP. Negative values indicate that hospitals reported acquisition costs below ASP and positive values indicate that hospitals reported acquisition costs above ASP.

We used the volume-weighted sum of all survey-eligible NDCs' ASP payment rates in order to produce a representative estimate of aggregate Medicare payments that would be comparable to hospitals' aggregate acquisition costs reported for those NDCs. This approach is consistent with longstanding OPPS principles of basing payment policy on observed utilization and resource use. We believe it is appropriate to compare hospitals' total acquisition costs to this weighted sum of ASPs rather than compare average acquisition costs to ASP because total acquisition costs encompass both the reported per-unit cost and the reported purchase volume for each NDC. In the absence of weighting by reported per-unit cost, drugs that encompass a very low percentage of hospitals' total acquisition costs could exert a disproportionate influence on the aggregate margin between acquisition costs and ASPs. And in the absence of weighting by reported purchase volume, the ASPs for drugs with relatively low reported volume but atypical acquisition costs could exert a disproportionate influence on the aggregate margin. By contrast, the volume-weighted approach ensures that the ASPs for the drugs representing a larger share of total purchasing activity contribute more significantly to the estimated margin. We will illustrate using the following fictitious example:

- Ten units of NDC 1 were purchased for $8 (average acquisition cost of $0.80 per unit) and NDC 1 has an adjusted ASP [94] of $1. The volume-weighted ASP is $10. NDC 1 was reported as purchased with a margin of minus 20 percent, or 20 percent below ASP.
- One unit of NDC 2 was purchased for $14 (average acquisition cost of $14 per unit) and NDC 2 has an adjusted ASP of $10. The volume-weighted ASP is $10. NDC 2 was reported as purchased at a margin of plus 40 percent, or 40 percent above ASP.

Aggregating the two above NDCs, the total acquisition cost is $22 ($8 + $14) and the volume-weighted sum of ASPs is $20 ($10 + $10). Calculating the percent difference yields a plus 10 percent margin, calculated as 100 * (($22 − $20)/$20). However, if no volume weighting methodology was applied, the sum of ASPs would be $11, and calculating the percent difference would yield a plus 100 percent margin, calculated as 100 * (($22 − $11)/$11).

We also considered weighting ASP payment rates for survey-eligible drugs by outpatient claims volume for survey-relevant HCPCS codes. We recognize the value of using OPPS claims data as it directly reflects real-world utilization. However, we did not adopt this approach because we believe it is appropriate to rely on a consistent survey-based framework for both acquisition costs and volume measures. We believe that weighting by survey-reported purchase volume avoids potential inconsistencies between external claims data and survey responses, ensures that the resulting margins are fully grounded in the reported acquisition cost data, better reflects the distribution of hospital drug purchasing activity as captured via the survey instrument, and is consistent with the statutory objective of approximating average acquisition cost in a manner that is both representative and methodologically sound. However, we seek comment on this approach to volume weight the average acquisition cost based on survey utilization data rather than OPPS claims data utilization.

We performed this acquisition cost margin calculation separately for non-340B and 340B drug purchases to analyze the data in the same manner in which it was collected. We then calculated acquisition cost margins using different ASP benchmarks, at different levels of data aggregation, and across a variety of scenarios to detect specific trends and variations in the submitted data. First, given that a drug's ASP can vary by quarter, we calculated each margin using both the mean ASP and median ASP across the four quarters of the specified time period (Q3 of 2024 to Q2 of 2025). Determining acquisition costs relative to both the median and mean ASP ensured that we properly accounted for any fluctuations in payment rate over time while mitigating the influence of any quarters with abnormal payment rates and allowed us to assess any differences in the margins that resulted from the two ASP benchmarks. Second, we calculated margins at the NDC level as well as aggregated to the HCPCS level; in the latter, acquisition costs were adjusted to the HCPCS level using the billing units per NDC package. Third, we calculated margins stratified by drug therapeutic class and hospital characteristics (340B participation status, ODACS drug purchase volume, outpatient drug claims billing volume, hospital size, rurality, geographic location, GPO membership, GPO discount amount, and teaching status). These various analytic scenarios were all undertaken to determine the differential between reported acquisition costs and ASP along relevant stratifications and characteristics as well as validate the robustness of the findings used in this proposal.

(2) Selection of a Methodology To Identify and Trim Outliers

In analyzing the survey data, it is appropriate to mitigate the influence of extreme and potentially anomalous observations that may reflect atypical purchasing arrangements, data anomalies, or reporting inconsistencies and could distort estimates of hospital drug acquisition costs. Consistent with standard statistical practice and our general approach under the OPPS to ensure that payment methodologies are

[93] ASP plus 0 is the ASP without any drug-specific payment rate add-ons (ASP plus 6 percent for most drugs and biologicals, ASP plus 8 percent for qualifying biosimilar products, or AMP plus 3 percent for select other drugs and biologicals).

[94] Since ASPs are reported by HCPCS billing unit, ASPs were adjusted to the NDC package units where necessary using an NDC–HCPCS adjustment factor.

based on representative data, we considered two different methods for identifying and excluding anomalous survey responses from the dataset. In both methods, the outlier identification and trimming process was performed separately for 340B and non-340B drug acquisitions, producing tailored outlier thresholds based on the unique data distribution for each drug through each purchasing channel.

First, we considered a trimming approach that excludes all observations with a per-unit acquisition cost more than three standard deviations from the geometric mean per-unit cost for each NDC. This approach is consistent with our standard methodology for processing extreme outliers to develop policy under the OPPS.[95] Application of the geometric mean trimming methodology necessitated removal of NDCs for which fewer than 10 survey respondents reported their purchase because outlier values cannot be detected with nine or fewer observations using this method.

We also considered the Tukey interquartile range (IQR) method[96] as an alternate outlier trimming approach and tested the impact of excluding outliers using the geometric mean approach compared to the IQR-based approach. Using the geometric mean approach to trim outliers removed 2,051 survey records (defined as the unique combination of hospital, NDC, and 340B or non-340B purchase from each survey response), or 1.3 percent of the total 160,430 original records while using the IQR approach to trim outliers removed 15,563 records, or 9.7 percent of the total 160,430 records. Upon manual review of the survey responses that were trimmed using each outlier approach and the data distribution for each NDC, we believe that the IQR approach erroneously identified some records as outliers despite their per-unit acquisition cost being generally in-line with the overall data distribution for that NDC. This is likely due to the distributional characteristics of the survey data, including evidence of skew in the distribution of reported acquisition costs for some NDCs. It has been established that the effectiveness of Tukey's IQR lessens when data are skewed and may lead to overidentification of observations as outliers.[97] [98] [99] In addition, we are concerned about the large number of survey records removed by the IQR trimming methodology, as one of our goals in conducting this survey is to analyze survey-reported drug acquisition costs using the largest amount of reasonable data received from hospitals as possible. Consequently, we do not propose to adopt the IQR-based outlier trimming methodology.

Rather, we propose to use the geometric mean approach to exclude identified outlier observations from the analyses used to estimate acquisition cost relationships. Specifically, we propose to trim records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC. We propose this approach to maintain consistency with the standard OPPS outlier trimming methodology. It also ensures that we retain the maximum number of responses with nonextreme values to estimate acquisition cost relationships from the survey data. By ensuring that the resulting estimates are based on data that are representative of typical hospital acquisition costs and are not unduly influenced by a small number of extreme observations, this approach is consistent with our longstanding objective of analyzing reliable and representative data to determine payment policy changes. We seek comment on our proposal to trim records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC.

(3) Application of Data Refinements To Remove Anomalous Data

Consistent with our general approach to ensuring that payment methodologies are based on reliable and internally consistent data, we reviewed the survey responses for values that are not plausible given statutory requirements that covered entities cannot be required to pay more than the 340B ceiling price for drugs acquired under the 340B Program or that exhibit clear inconsistencies in reporting. We identified five scenarios in which reported data displayed anomalous values, which appear to be the result of data entry error, miscalculation, or other respondent confusion. Below we detail each identified scenario and the number of survey records that fall into each. We propose to exclude these survey responses from the analyses used to assess acquisition cost relationships to ensure that these calculations are not unduly influenced by implausible values.

First, we identified instances in which respondents that were not participating in the 340B Program during the relevant study time period (as verified using the 340B Office of Pharmacy Affairs Information System (340B OPAIS)) reported acquisition cost data in the 340B fields of the survey. These observations likely reflected reporting errors, given that these hospitals could not have accessed 340B discounts. Therefore, we propose to exclude 340B acquisition cost data submitted by non-340B hospitals from analyses of 340B acquisition cost to maintain consistency with the survey design and statutory framework. This proposed refinement removes 850 records out of the 160,430 records received through the survey.

Second, we identified instances in which respondents reported purchasing drugs through the 340B Program for 58 NDCs that did not have a 340B ceiling price during the survey time period. These observations may reflect reporting errors, such as reporting acquisition data for the incorrect NDC within a drug that was intended, given that no 340B agreement, or associated discount, was available for these NDCs. In some cases, where these NDCs had 340B ceiling prices during other quarters outside the survey time period, these observations may be the result of respondent confusion over survey reporting period or the time period when these NDCs had a 340B ceiling price in place. Alternatively, hospitals may have acquired non-340B NDCs through the 340B Prime Vendor Platform (PVP) without receiving a 340B discount price;[100] while hospitals may have

[95] *https://www.cms.gov/files/document/2026-nfrm-opps-claims-accounting.pdf.*

[96] Under this approach, for each NDC, we would calculate the first quartile (Q1) and third quartile (Q3) of per-unit acquisition cost based on the empirical distribution of hospitals' reported average acquisition cost values, and define the IQR as Q3 minus Q1. We would then establish outlier thresholds as follows: (1) an upper threshold equal to Q3 plus 1.5 times the IQR; and (2) a lower threshold equal to Q1 minus 1.5 times the IQR. Observations with per-unit acquisition costs that fall outside these thresholds are identified as outliers. Application of the IQR-based trimming methodology would necessitate removal of NDCs for which fewer than four survey respondents reported their purchase because outlier values cannot be detected with three or fewer observations using the Tukey IQR method.

[97] M. Hubert and E. Vandervieren, ''An adjusted boxplot for skewed distributions,'' *Computational Statistics & Data Analysis* 52, no. 12 (August 15, 2008): 5186–5201, *https://doi.org/10.1016/j.csda.2007.11.008.*

[98] Neil C. Schwertman, Margaret Ann Owens, and Robiah Adnan, ''A simple more general boxplot method for identifying outliers,'' *Computational Statistics & Data Analysis* 47, no. 1 (August 1, 2004): 165–174, *https://doi.org/10.1016/j.csda.2003.10.012.*

[99] Arefeh Mazarei et al., ''Online boxplot derived outlier detection,'' *International Journal of Data Science and Analytics* 19 (2025): 83–97, *https://doi.org/10.1007/s41060-024-00559-0.*

[100] The 340B PVP website states that ''The [PVP] . . . works with 155 manufacturers to obtain lower

considered these purchases to be 340B acquisitions for the purposes of their survey reporting, evaluating these responses as part of 340B margin calculations would provide an inaccurate picture of the acquisition costs for NDCs with 340B discounts. We also did not elect to evaluate these responses as part of non-340B margin calculations as it was impossible to separate instances of reporting errors from non-340B purchases made through the 340B PVP. Therefore, we propose to exclude 340B survey responses for these NDCs without 340B ceiling prices from analyses of both 340B and non-340B acquisition cost to maintain consistency with the survey design and statutory framework. This proposed refinement removes 839 records out of the 160,430 records received through the survey.

Third, we identified a small number of responses from hospital subunits that submitted identical data to their parent unit. Hospital subunits were identified as entities where the third digit of its CMS Certification Number (CCN) is T (representing inpatient rehabilitation units) or S (representing psychiatric units). Parent units were identified as entities where all six digits of its CCN are numeric.[101] To identify a parent unit for each subunit, the T or S in the third digit was replaced with the numeric digit associated with the provider type of that subunit (either 0, 2, 3, or 4). If this replacement yielded more than one possible parent unit, the subunit was further matched with a parent unit based on CCN name and ZIP code. Identical parent–subunit data were identified as survey responses with the exact same number of total units and total net acquisition costs reported for the exact same NDCs. These observations likely reflect duplicative data reported by one submitter who was responsible for multiple entities. Accordingly, we propose to exclude these duplicative responses from subunits in favor of only retaining the equivalent responses from the parent unit. We identified 27 subunits with duplicative data to their parent unit, and this proposed refinement removes 4,799 records out of the160,430 records received through the survey.

Fourth, we identified instances in which reported acquisition costs for drugs purchased under the 340B Program exceeded the maximum applicable 340B ceiling price during the survey time period. By statute, covered entities cannot be required to pay more than the 340B ceiling price for drugs acquired under the 340B Program. Such observations are not representative of actual acquisition costs and are likely attributable to reporting or data entry errors (for example, miscalculations or incorrect decimal placement). Accordingly, we propose to exclude 340B drug purchases with average acquisition costs above the maximum ceiling price from our analysis. This proposed refinement removes 4,667 records out of the 160,430 records received through the survey.

Fifth, we observed that certain respondents reported units for specific drugs, including clotting factors and certain respiratory therapies, in international units (IU) or milligrams (MG) rather than the required NDC-based units. IU is the HCPCS billing unit for the clotting factors and MG is the HCPCS billing unit for the respiratory therapies;[102] however, because the survey requires reporting at the NDC level, the use of IU- or MG-based units would result in substantial distortions in calculated per-unit acquisition costs, typically producing extremely high reported unit volumes and correspondingly low per-unit costs. These observations are not comparable to properly reported NDC-level data. To avoid possible selection bias that may result from specifically excluding responses with units reported in IU or MG, we therefore propose to exclude all survey responses for affected NDCs with units reported in IU or MG from the analysis. This proposed refinement removes 4,398 records out of the 160,430 records received through the survey. We note, if CMS would have included this data, the acquisition cost margins would have been significantly lower than Medicare payment rates.

The exclusion of these anomalous observations, in conjunction with the application of the outlier trimming methodology and other data standardization approaches described above, improves the reliability and validity of the resulting estimates of acquisition costs. In particular, it ensures that the resulting estimates reflect plausible and internally consistent acquisition costs while minimizing the influence of erroneous or noncomparable data. Moreover, applying these five proposed data refinement exclusions did not have a substantial impact on the overall number of survey records included in analyses of acquisition cost. Collectively, these five refinements removed 14,313 records out of the 160,430 records received through the survey. In other words, after applying these five exclusions, there remained 146,117 survey records in the dataset, 91.1 percent of the total 160,430 original records we received from respondents. We note that there are some overlaps in each individual exclusion of survey records, where the same survey record was excluded for meeting more than one exclusion criterion.

For each of the five scenarios discussed above, we propose to exclude survey responses for values that are not plausible given statutory requirements or that exhibit clear inconsistencies in reporting. Specifically, we propose to exclude survey responses that were identified as meeting at least one of the five scenarios listed above based on our manual review of the data, ASP pricing files, Health Resources and Services Administration (HRSA) 340B ceiling pricing files, and relevant policy and billing guidance. We believe that this approach represents the most appropriate and methodologically sound means of estimating the typical margin in the survey data between hospitals' survey-reported acquisition costs and ASP. We solicit comment on our approach to identifying and excluding anomalous data, as well as on the overall methodology used to evaluate the survey data for purposes of this proposal.

c. OPPS Drug Acquisition Cost Survey Results

(1) Survey Response Rate and Respondent Characteristics

We first determined the response rate and hospital characteristics of survey respondents to understand which entities had submitted a survey response, then compared them to the characteristics of nonrespondents and the survey-eligible population to assess their representativeness relative to the overall population. We also applied a methodology to refine the population of survey-eligible hospitals to more precisely reflect those entities with meaningful outpatient acquisition volume for drugs included in the survey.

drug pricing for [340B covered entities] on non-340B items, such as vaccines . . . .''

[101] Hospital type for each parent unit was identified based on the final four digits of its CCN. Short-term (general and specialty) hospitals were identified as those in the range 0001–0899; long-term care hospitals were identified as those in the range 2000–2299; rehabilitation hospitals were identified as those in the range 3025–3099 children's hospitals were identified as those in the range 3300–3399; psychiatric hospitals were identified as those in the range 4000–4499; and IPPS-exempt freestanding cancer hospitals were identified as CCNs listed on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/pps-exempt-cancer-hospitals-pchs,*.

[102] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP-Report-in-units-other-than-NDC.pdf.*

Approximately 43.6 percent of the 4,494 entities eligible for OPPS payment (hereinafter referred to as ''survey-eligible hospitals'') submitted a survey response and approximately 29.8 percent of eligible hospitals reported that they had acquisition costs during the survey time period. We received a number of responses, many of which appeared to be coordinated form letters, from eligible hospitals indicating that they would not be providing their acquisition data and explaining their reasons for not doing so. Before refining the population, approximately 34.9 percent of non-340B hospitals and approximately 23.1 percent of 340B hospitals responded to the survey and reported that they had acquisition costs for survey-eligible drugs during the surveyed time period (Table 49).

TABLE 49: DESCRIPTIVE SURVEY RESPONDENT STATISTICS

Category	Non-340B Hospitals	340B Hospitals	Total Hospitals
Number of Survey-Eligible Hospitals	2537	1957	4494
Number of Overall Respondents	1421	537	1958
Percent of Overall Respondents	56.0%	27.4%	43.6%
Number of Respondents Reported Data	885	453	1338
Percent of Respondents Reported Data	34.9%	23.1%	29.8%

However, claims analysis of the eligible hospital population determined that a subset of entities that were included in the survey had zero outpatient claims for survey-relevant HCPCS codes during the survey study period. Many of these entities did not submit a survey response, likely because they did not acquire any survey-relevant drugs during the time period. Other entities were hospital subunits that did not submit a survey response or submitted a response reporting zero acquisition costs, but their parent unit submitted a survey response reporting acquisition data.

Consequently, we applied population refinements to consolidate subunits with their parent units and to remove entities from the survey that neither reported acquisition costs nor had outpatient billing volume for HCPCS codes corresponding to NDCs included in the survey during the specified time period. These refinements resulted in a slightly smaller population that may more appropriately reflect the universe of eligible hospitals with meaningful and relevant outpatient drug acquisition volume. This population is almost exclusively composed of short-term acute care hospitals: 2,977 out of 3,147 total CCNs (94.6 percent) in the refined population are short-term acute care hospitals as compared to 3,018 out of 4,494 total CCNs (67.2 percent) in the original population. This change occurred for two reasons. First, by consolidating subunits with their parent unit, all subunits (that is, psychiatric units and inpatient rehabilitation units), which had accounted for 742 (16.5 percent) in the original population no longer appear in the population as distinct hospitals. Second, this refinement also markedly reduced the number of psychiatric hospitals, long-term care hospitals, and rehabilitation hospitals in the refined population because the majority of these hospitals neither reported acquisition costs nor billed any relevant outpatient claims.

Of this refined study population, approximately 41.4 percent of hospitals responded to the survey and reported that they had acquisition costs during the surveyed study period. Additionally, approximately 53.3 percent of non-340B hospitals and approximately 28.6 percent of 340B hospitals in the refined population responded to the survey and reported that they had acquisition costs during the surveyed study period (Table 50). For discussion of analyses that we undertook to confirm that this response rate is sufficiently large to yield a statistically valid sample, we refer readers to the calculation of confidence intervals in section (3) Population Weight Adjustment and Statistical Validity.

TABLE 50: DESCRIPTIVE SURVEY RESPONDENT STATISTICS (REFINED POPULATION)

Category	Non-340B Hospitals	340B Hospitals	Total Hospitals
Refined Number of Survey-Eligible Hospitals Number	1639	1508	3147
Refined Number of Respondents Reported Data	873	431	1304
Refined Percent of Respondents Reported Data	53.3%	28.6%	41.4%

Using the refined population, we then compared observable hospital characteristics of survey respondents that reported acquisition costs to the characteristics of the survey-eligible population (Table 51). Compared to the overall survey-eligible population, hospitals that responded to the survey and reported acquisition cost data were slightly more likely to have lower claims billing volume, be smaller, be located in a rural area, and not be major teaching hospitals.

Given these slight differences in hospital characteristics between respondents and the overall population, we performed inverse probability weighting (IPW) to confirm that respondents' data yielded statistically representative estimates of hospital outpatient drug acquisition costs. We refer readers to the discussion of IPW-adjusted margins in section (3) Population Weight Adjustment and Statistical Validity.

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TABLE 51: COMPARISON OF HOSPITAL RESPONDENTS VS NONRESPONDENTS (REFINED POPULATION)

Hospital Characteristic	All Survey-Eligible Hospitals		Respondents Reporting Acquisition Cost Data		Nonrespondents	
	Number	Percentage	Number	Percentage	Number	Percentage
All Hospitals	***3,147***	***100.0%***	***1,304***	***100.0%***	***1,804***	***100.0%***
Outpatient Drug Claims Volume						
Bottom Quintile	591	18.8%	287	22.0%	287	15.9%
Second Quintile	622	19.8%	327	25.1%	284	15.7%
Third Quintile	626	19.9%	256	19.6%	364	20.2%
Fourth Quintile	627	19.9%	221	16.9%	403	22.3%
Top Quintile	628	20.0%	160	12.3%	466	25.8%
No Billing	53	1.7%	53	4.1%	0	0.0%
Hospital Size (Number of Beds)						
Bottom Quintile	502	16.0%	263	20.2%	230	12.7%
Second Quintile	542	17.2%	236	18.1%	293	16.2%
Third Quintile	647	20.6%	267	20.5%	373	20.7%
Fourth Quintile	715	22.7%	284	21.8%	424	23.5%
Top Quintile	741	23.5%	254	19.5%	484	26.8%
Geographic Rurality						
Metropolitan	2,320	73.7%	937	71.9%	1,356	75.2%
Micropolitan	544	17.3%	224	17.2%	315	17.5%
Rural	283	9.0%	143	11.0%	133	7.4%
Census Region						
New England	136	4.3%	33	2.5%	101	5.6%
Middle Atlantic	346	11.0%	129	9.9%	212	11.8%
South Atlantic	518	16.5%	219	16.8%	295	16.4%
East North Central	484	15.4%	166	12.7%	314	17.4%
East South Central	266	8.5%	129	9.9%	128	7.1%
West North Central	237	7.5%	87	6.7%	148	8.2%
West South Central	504	16.0%	295	22.6%	199	11.0%
Mountain	226	7.2%	100	7.7%	124	6.9%
Pacific	388	12.3%	125	9.6%	263	14.6%
Puerto Rico	42	1.3%	21	1.6%	20	1.1%
Teaching Status						
Major Teaching	400	12.7%	134	10.3%	265	14.7%
Not Major Teaching	2,657	84.4%	1,128	86.5%	1,495	82.9%
Unknown	90	2.9%	42	3.2%	44	2.4%

Note: The number of hospitals shown in the "Respondents Reporting Acquisition Cost Data" and "Nonrespondents" columns does not sum to the total number of hospitals in the "All Survey-Eligible Hospitals" column because 39 survey respondents that reported no drug acquisitions during the survey period are excluded from this table. Of these hospitals, 28 (71.8 percent) were non-340B hospitals and 11 (28.2 percent) were 340B hospitals. The 39 survey respondents that reported no drug acquisitions during the survey period are excluded from Table 51. These hospitals generally had low outpatient drug billing volume, tended to be smaller facilities, and were predominantly located in metropolitan areas. The hospitals were geographically distributed across Census regions, and only one hospital was classified as a major teaching hospital.

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(2) Margins Between Survey-Reported Hospital Acquisition Costs and Volume-Weighted ASP

Using the methodology, refinements, and processes discussed throughout Section (2)(b) Data Analysis and Methodology, we evaluated the received survey data to determine the difference between hospitals' survey-reported acquisition costs and ASP-based Medicare payment amounts. We first identified the percent margin between aggregate acquisition costs and volume-weighted ASP for both non-340B and 340B drug acquisitions, then performed an analogous calculation to identify the margin between 340B ceiling prices and ASP as additional context for the 340B acquisition cost margins. Next, we tested alternate methodological specifications to evaluate whether these margins varied depending on the methods used. Finally, we stratified margins by individual therapeutic classes to identify possible variation in acquisition costs relative to ASP along drug type.

The survey provides valuable information regarding hospitals' drug acquisition costs. Following the GAO recommendation to validate Medicare payment rates using hospital acquisition costs, we assessed the survey data for trends where acquisition cost did not align with Medicare payment. The most immediately evident difference was between Medicare payment rates and acquisition cost data for 340B-acquired drugs by 340B-participating hospitals. Based on the survey response data and applying the methodologies discussed above, we found that for drugs acquired through the 340B Program, hospitals' reported acquisition costs during the specified time period were approximately 33.4 percent below both the mean and the median ASP. For drugs acquired outside of the 340B Program, hospitals' survey-reported acquisition costs during the specified time period were approximately 2.7 percent above the mean ASP and 2.8 percent above the median ASP.

To help validate these findings, we compared aggregate 340B ceiling prices from HRSA for drugs included in the survey during the corresponding survey period to ASP amounts.[103] Based on this analysis, during the survey study period 340B ceiling prices were, in aggregate, 28.0 percent below the mean ASP and 29.2 percent below the median ASP, respectively. These findings help validate the survey response data for 340B acquired drugs, as the ceiling price average discount is generally representative of the maximum acquisition cost and minimum discount, though hospitals can negotiate additional discounts resulting in a sub-ceiling acquisition cost. This is reflected in the survey results where the aggregate 340B acquisition cost margin is approximately 33.4 percent below the mean ASP—several percentage points lower than the aggregate ceiling price margin of 28.0 percent below the mean ASP.

We sought to ensure that the resulting margins precisely reflected the relationship between hospitals' acquisition costs and ASP, and did not manifest substantial changes under different methodological specifications. To do so, we tested the impact of weighting acquisition cost margins by OPPS claims volume and retaining 340B survey responses above the maximum ceiling price (Table 52). Although we are not proposing to adopt these alternative methodologies at this time for the reasons outlined in the methodology section, calculating acquisition cost margins with these specifications emphasizes two key points about 340B-acquired drugs. First, regardless of how one analyzes the data, there are considerable differences between hospitals' acquisition costs for 340B-acquired drugs and ASP-based payment amounts for 340B drugs. Second, these alternate methodologies had minimal impact on the acquisition cost margins for 340B-acquired drugs; regardless of calculation methodology, hospitals' survey-reported acquisition costs remained relatively consistent between approximately 29.9 percent and 33.4 percent below the average ASP and between 29.8 percent and 33.4 percent below the median ASP.

Application of different methodological specifications resulted in slightly more variation in the estimated margin between hospitals' survey-reported acquisition costs and mean or median ASP-based payments for drugs acquired outside the 340B Program. This greater variability could be attributed to wider distributional spread in the reported acquisition costs for non-340B drugs; this, in turn, could cause the non-340B margins to be more sensitive to application of different weighting methodologies.

TABLE 52: ODACS STATISTICAL DATA METHODOLOGIES AND RESULTS

Aggregate Margin Calculations: Methodology Specifications			Acquisition Cost to ASP Margin			
			Non-340B		340B	
			Mean ASP Margin	Median ASP Margin	Mean ASP Margin	Median ASP Margin
Geometric Mean Outliers Removed	Weighted by Survey Purchase Volume	Responses > Ceiling Price Included	2.7%	2.8%	31.9%	31.8%
		Responses > Ceiling Price Excluded			33.4%	33.4%
	Weighted by Outpatient Claims Volume	Responses > Ceiling Price Included	6.7%	6.7%	–29.9%	–29.8%
		Responses > Ceiling Price Excluded			–31.2%	–31.1%

[103] The 340B ceiling prices are the maximum statutory amounts drug manufacturers can charge covered entities for outpatient prescription drugs. They are calculated by subtracting the unit rebate amount (URA) which is the Medicaid rebate manufacturers must pay to the government from the average manufacture price (AMP) which is the average price paid to the manufacturer by wholesalers for a given drug.

To assess whether the magnitude of margins remained the same across different drug categories, we also examined acquisition cost margins by therapeutic class [104] for both 340B acquired and non-340B-acquired drugs . Hospitals' survey-reported 340B acquisition costs were at least 28.9 percent below the mean ASP—and for most therapeutic classes lower than that—for drugs in all high-spending therapeutic classes (that is, those with more than $100 million in reported acquisition costs) (Table 53). Again, this reinforces the significant, and consistent, differences between hospitals' acquisition cost for 340B acquired drugs and ASP for these drugs regardless of therapeutic class.

The margins for non-340B drugs displayed in greater variation relative to the 340B drugs, which is likely attributable to greater heterogeneity in drug mix, provider type, and purchasing arrangements present outside the 340B Program. For instance, only certain drugs and biologicals are able to be acquired through the 340B Program and only certain types of hospitals can enroll as 340B participants. These restrictions necessarily limit which drugs and hospitals can be included in the 340B calculations, leading to a somewhat more homogenous population. These restrictions do not play a role in the non-340B calculations. Additionally, and perhaps most significantly, certain types of 340B-participating hospitals have historically been prohibited from purchasing covered outpatient drugs through GPO arrangements,[105] which limits the purchasing arrangements applicable to 340B drugs, while non-340B drugs can be purchased under a variety of GPO or other buying group arrangements.

TABLE 53: ACQUISITION COST MARGINS BY THERAPEUTIC CLASS FOR 340B DRUGS

Therapeutic Class	340B	
	Mean ASP Margin	Median ASP Margin
Antineoplastics and Adjunctive Therapies	–28.9%	–28.8%
Hematopoietic Agents	–38.3%	–37.8%
Endocrine and Metabolic Agents	–52.6%	–52.8%
Passive Immunizing and Treatment Agents	–30.8%	–30.4%
Gastrointestinal Agents	–29.3%	–29.1%
Psychotherapeutic and Neurological Agents	–31.2%	–31.3%
Miscellaneous	–29.6%	–29.6%
Analgesics	–71.4%	–71.4%
Neuromuscular Agents	–31.8%	–31.9%

(3) Application of Population Weight Adjustment and Calculation of Confidence Intervals To Assess Statistical Validity

In accordance with section 1833(t)(14)(D)(iii) of the Act, after completing initial analysis of survey respondents' acquisition costs, we evaluated whether survey respondents comprised a large sample that is sufficient to generate statistically significant and representative estimates of hospitals' acquisition costs. To do so, we conducted sensitivity analyses using inverse probability weighting (IPW) and confidence intervals, which we believe support the statutory objective of obtaining acquisition cost estimates from survey responses that are accurate and representative of the outpatient drug acquisition costs incurred by all hospitals paid under the OPPS.

(i) IPW Methodology

[104] Therapeutic class assignments were based on the Medi-Span Generic Product Identifier (GPI) classification system.

[105] *https://www.hrsa.gov/sites/default/files/hrsa/opa/prohibition-gpo-participation-02-07-13.pdf.*

IPW is a widely used statistical technique in survey research [106] [107] [108] [109] [110] to ensure that sample data produce estimates that accurately represent the population of interest. We applied IPW to account for the potential underrepresentation or overrepresentation of hospitals with particular characteristics among survey respondents and to evaluate whether acquisition cost margins derived from survey responses sufficiently reflected outpatient drug acquisition costs for all OPPS hospitals.

For purposes of the IPW analysis, we constructed respondent and nonrespondent populations that align with the refined hospital population discussed in above in (1) Survey Response Rate and Respondent Characteristics. We defined the respondent population as hospitals that submitted a survey response reporting the purchase of at least one surveyed NDC during the survey study period. We defined the nonrespondent population as survey-eligible hospitals that did not submit a survey response but billed at least one Fee-For-Service outpatient claim associated with a survey-relevant HCPCS code during the same period. Because acquisition cost margins were calculated separately for drugs purchased through the 340B Program and drugs purchased outside the 340B Program, we further stratified hospitals based on evidence of 340B drug use. Hospitals were identified as 340B participants using HRSA's 340B OPAIS enrollment information and claims submitted with 340B modifiers. Hospitals that neither submitted an ODACS response nor billed relevant outpatient claims during the survey period were excluded from the IPW-adjusted population. Subunits were collapsed with their corresponding parent unit prior to constructing the respondent and nonrespondent populations.

After identifying the respondent and nonrespondent groups, we calculated response propensity scores using logistic regression models based on observed hospital characteristics, including number of beds, teaching hospital status, geographic rurality, and Census division. Propensity scores were estimated separately for hospitals purchasing drugs outside the 340B Program and hospitals purchasing drugs through the 340B Program. A higher propensity score means that the hospital was more likely to submit a survey response; a lower propensity score means that the hospital was less likely to submit a survey response.

We then calculated inverse probability weights equal to the inverse of each hospital's estimated probability of responding to the survey. Hospitals with a higher likelihood of responding received smaller weights, while hospitals with a lower likelihood of responding received larger weights. The weights were used to adjust for differential representation of hospital characteristics between the respondent sample and the broader population of survey-eligible hospitals. Down-weighting hospitals with a high probability of response (which are overrepresented in the received sample) while upweighting CCNs with a low probability of response (which are underrepresented in the received sample) accounted for the differential representation of hospital characteristics in the sample as compared to the full population.

Finally, we calculated the IPW-adjusted acquisition cost margins by first applying the calculated weights to hospitals' average acquisition costs and corresponding ASP-based payment amounts, then recalculating aggregate acquisition cost margins by finding the difference between the IPW-adjusted acquisition costs and IPW-adjusted ASP-based payment and then dividing that difference by the IPW-adjusted ASP-based payment. We also applied the same methodology when calculating IPW-adjusted margins between acquisition costs and 340B ceiling prices.

(ii) Confidence Intervals Methodology

To evaluate whether the number of survey responses was sufficient to produce statistically valid estimates of hospitals' acquisition costs, we calculated confidence intervals for both unadjusted and IPW-adjusted acquisition cost margins. The confidence intervals provide measures of whether the survey response rate adequately captures true population-level results. When response rate is insufficiently low, confidence intervals are very wide due to the high degree of uncertainty regarding where the true result lies. Conversely, when response rate is sufficient, confidence intervals become narrower as uncertainty lessens.

We calculated confidence intervals using a bootstrap methodology. Specifically, we repeatedly sampled with replacement from the original survey dataset and recalculated acquisition cost margins for each repeated sample. We repeated this process 10,000 times to generate distributions of unadjusted and IPW-adjusted acquisition cost margin estimates. We then identified the 95 percent confidence intervals for each acquisition cost margin estimate using the 2.5th percentile as the lower bound and the 97.5th percentile as the upper bound.

(iii) Results of Population Weight Adjustments and Confidence Intervals From ODACS Data

Application of inverse probability weighting improved the alignment between the distribution of respondent hospital characteristics and the broader population of survey-eligible hospitals. We found that IPW-adjusted respondent characteristics more closely resembled the full population across measures such as rural/urban, teaching status, Census division, and 340B participation (Table 54).

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[106] ''Behavioral Risk Factor Surveillance System: Weighting the Data (2011 Weighting Formula),'' U.S. Centers for Disease Control and Prevention, last modified July 19, 2013, *https://www.cdc.gov/brfss/annual_data/2011/2011_weighting.htm.*

[107] ''National Health and Nutrition Examination Survey—Weighting,'' U.S. Centers for Disease Control and Prevention, n.d., *https://wwwn.cdc.gov/nchs/nhanes/tutorials/weighting.aspx.*

[108] ''Weighting,'' U.S. Census Bureau, last modified January 12, 2022, *https://www.census.gov/programs-surveys/cps/technical-documentation/methodology/weighting.html.*

[109] ''Weighting,'' U.S. Census Bureau, last modified August 19, 2022, *https://www.census.gov/programs-surveys/sipp/methodology/weighting.html.*

[110] ''Consumer Expenditures and Income: Calculation,'' U.S. Bureau of Labor Statistics, last modified September 12, 2022, *https://www.bls.gov/opub/hom/cex/calculation.htm.*

TABLE 54: POPULATION WEIGHT ADJUSTMENT BY HOSPITAL CHARACTERISTIC

Hospital Characteristic	Non-340B Drugs			340B Drugs		
	ODACS-Eligible Population	Unadjusted ODACS Respondents	IPW-Adjusted ODACS Respondents	ODACS-Eligible Population	Unadjusted ODACS Respondents	IPW-Adjusted ODACS Respondents
340B Enrollment						
340B Hospital	48.1%	32.8%	50.0%	100.0%	100.0%	100.0%
Non-340B Hospital	51.9%	67.2%	50.0%	N/A	N/A	N/A
Number of Beds						
Bottom Quintile	15.8%	20.0%	16.2%	7.4%	9.6%	6.9%
Second Quintile	17.1%	18.3%	16.9%	13.8%	16.7%	13.7%
Third Quintile	20.6%	20.6%	20.8%	17.5%	17.0%	17.7%
Fourth Quintile	22.7%	21.6%	23.4%	26.4%	27.0%	26.6%
Top Quintile	23.8%	19.6%	22.7%	35.0%	29.7%	35.2%
Rurality						
Metropolitan	73.8%	71.8%	74.6%	71.8%	69.5%	71.9%
Micropolitan	17.3%	17.2%	16.7%	20.0%	19.2%	20.3%
Rural	8.9%	11.0%	8.7%	8.3%	11.3%	7.8%
Census Region						
New England	4.3%	2.6%	4.6%	4.8%	3.4%	4.5%
Middle Atlantic	10.9%	9.7%	10.7%	12.1%	9.8%	13.1%
South Atlantic	16.6%	16.8%	16.0%	14.1%	11.8%	15.0%
East North Central	15.5%	12.9%	16.3%	17.0%	18.4%	16.6%
East South Central	8.3%	9.9%	8.3%	8.6%	9.8%	8.6%
West North Central	7.5%	6.6%	7.0%	8.3%	8.1%	8.1%
West South Central	15.8%	22.7%	15.9%	12.9%	18.2%	12.6%
Mountain	7.2%	7.7%	6.4%	6.3%	3.9%	6.4%
Pacific	12.6%	9.7%	13.0%	15.4%	15.0%	14.6%
Puerto Rico	1.2%	1.4%	1.9%	0.5%	1.5%	0.5%
Teaching Status						
Major Teaching	12.8%	10.2%	11.8%	19.5%	16.7%	19.5%
Not Major Teaching	84.4%	86.6%	85.6%	77.3%	79.1%	77.4%
Unknown	2.8%	3.3%	2.6%	3.2%	4.2%	3.1%

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(iv) Weighted Adjusted Acquisition Cost Margins

We found that application of IPW had minimal impact on estimated acquisition cost margins for either non-340B drugs or 340B-acquired drugs. For drugs acquired outside the 340B Program, the analysis conducted estimated that acquisition costs were approximately 2.7 percent above the mean ASP prior to IPW adjustment and approximately 2.8 percent above the mean ASP after IPW adjustment. For drugs acquired through the 340B Program, the analysis estimated that acquisition costs were approximately 33.4 percent below the mean ASP prior to IPW adjustment and approximately 33.1 percent below the mean ASP after IPW adjustment. The consistency between unadjusted and IPW-adjusted results supports the robustness and representativeness of the acquisition

cost margins derived from survey responses (Table 55).

TABLE 55: EFFECT OF INVERSE PROBABILITY WEIGHT ADJUSTMENT ON ACQUISITION COST MARGINS AND 95 PERCENT CONFIDENCE INTERVALS (CI)

Aggregate Margin Calculations: Methodology Specifications		Acquisition Cost to Mean ASP Margin					
		Non-340B Drugs			340B Drugs		
		Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit
Responses > Ceiling Price Included	Unadjusted	+2.7%	–3.8%	+6.9%	–31.9%	–33.9%	–29.4%
	IPW-Adjusted	+2.8%	–1.6%	+6.5%	–31.6%	–33.4%	–29.3%
Responses > Ceiling Price Excluded	Unadjusted				–33.4%	–34.7%	–32.3%
	IPW-Adjusted				–33.1%	–34.3%	–32.1%

The 95 percent confidence intervals for both unadjusted and IPW-adjusted acquisition cost margins were not substantially different from each other, indicating the weighting adjustment had minimal impact on the resulting estimates. For non-340B drugs, the confidence intervals ranged from approximately 3.8 percent below the mean ASP to 6.9 percent above the mean ASP for unadjusted margin and between 1.6 percent below the mean ASP to 6.5 percent above the mean ASP for the IPW-adjusted margin. For 340B-acquired drugs, the confidence intervals were much narrower and ranged from approximately 34.7 percent to 32.3 percent below the mean ASP for the unadjusted margin and from 34.3 percent to 32.1 percent below the mean ASP for the IPW-adjusted margin (Table 55).

We believe the relatively narrow confidence intervals for 340B-acquired drugs support the statistical validity of the survey results on 340B drugs and indicate that the received sample is sufficiently large to produce reliable estimates of hospital outpatient drug acquisition costs for 340B drugs. We note that the confidence intervals for the non-340B drugs span a wider range of potential acquisition cost margins. This is expected given the greater distributional spread in the survey data for non-340B drugs, as discussed in this section V.B.2.8. of this proposed rule.

For an additional summary of our analysis of the survey results we refer readers to the 2026 Outpatient Prospective Payment System Drug Acquisition Cost Survey Technical Report which will be posted on the Medicare Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey website.[111] We solicit comment on our process for how we evaluated ODACS data to determine the magnitude of the margins between hospitals' survey-reported acquisition costs and ASP-based Medicare payment amounts.

C. CY 2027 OPPS Payment Methodology for 340B Purchased Drugs Based on Survey Results

As described previously, section 1833(t)(14)(D)(ii) of the Act requires the Secretary to conduct periodic surveys to determine the hospital acquisition cost for each SCOD for use in setting the payment rates for SCODs under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(I) of the Act provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug (which at the option of the Secretary, may vary by hospital group) as determined by the Secretary, taking into account the survey data collected under subparagraph (D) of section 1833(t)(14) of the Act. Based on our analysis of the survey data, the most immediately evident and significant difference found between Medicare payment and acquisition cost was for 340B drugs acquired by 340B-participating hospitals, where the selected methodology shows that aggregate acquisition costs are approximately ASP minus 33.4 percent. This indicates average acquisition costs that are 37.2 percent lower than the general OPPS payment rate (ASP plus six percent). These results clearly demonstrate that ASP plus 6 percent is not an appropriate payment proxy for hospitals that acquire drugs through the 340B Program. Consequently, we propose to adjust the OPPS payment policy for 340B drugs to better align payment with the acquisition costs demonstrated by the survey. Specifically, for CY 2027, as discussed further in this section V.C. of this proposed rule, we propose to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent.

Conversely, for non-340B drugs, after taking into account the survey data, we are proposing to maintain the current payment rate, which is generally ASP plus 6 percent, under the authority at 1833(t)(14)(A)(iii)(I) of the Act. As displayed in Table 52, the heterogeneity in acquisition costs for non-340B drugs is slightly greater than for 340B drugs; this variation has led us to believe this area warrants additional analysis by CMS and input from interested parties. The results of the survey for non-340B drugs generally indicate lower acquisition costs than current payment; however, the discrepancy is not as clear and significant as with 340B drugs. Therefore, we are continuing to analyze the data from this survey, aligning those reported costs with hospital claims billing patterns, to see if any additional significant trends exist that merit further adjustments to OPPS payment policy in future years. We are also assessing

[111] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey.*

billing patterns among those hospitals that did not respond. Finally, we collected and analyzed information on non-NDC-specific GPO discounts that hospitals receive and are still considering how these discounts could be factored into future analysis and policymaking. We will consider these issues for future rulemaking.

1. Statistically Significant Estimate

Under section 1833(t)(14)(D)(iii) of the Act, the periodic surveys conducted by the Secretary under 1833(t)(14)(D)(i) and (ii) of the Act must ''have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug.'' Our survey results meet this standard, particularly because hospital acquisition cost is a price measure.[112] Reliable price measures require far less sampling than quantity or revenue measures because markets tend to compress this distribution of prices across transactions but do not compress the distribution of quantities or expenditures.[113] Hospitals can differ in their acquisition cost on a 340B drug by a factor of 1000. While hospital acquisition cost for a branded drug would not be exactly equal across hospitals in the 340B Program, it would not differ by a factor of 1000 and rarely even a factor of 2. Because the standard errors of the 340B-hospital sample mean and the non-340B-hospital sample mean are each proportional to the standard deviation of the underlying population, a compressed price distribution translates directly into small standard errors and high statistical significance.[114]

As discussed previously and shown in Table 54, the 95 percent confidence intervals for 340B drugs were relatively narrow, ranging from approximately 34.7 percent to 32.3 percent below ASP for the unadjusted margin and from approximately 34.3 percent to 32.1 percent below ASP for the IPW-adjusted margin. These results support the statistical validity of the estimated acquisition cost margins and indicate that the survey data provide reliable estimates of the acquisition cost discounts realized by 340B hospitals relative to ASP. These sampling requirements for price measurement are well known in national accounting. For example, the Department of Labor's Bureau of Labor Statistics measures prices for the Consumer Price Index (CPI) using about 100,000 commodity-and-service price observations per month, while the Producer Price Index (PPI) uses approximately 64,000 monthly price quotations from about 16,000 establishments.[115] These samples are tiny relative to the transactions they are designed to represent: the CPI commodity-and-service sample alone is less than 0.01 percent of such payments.[116]

In our efforts to obtain data from a statistically significant sample of hospitals paid under the OPPS, we initially included for survey participation 100 percent of OPPS hospitals. From this, we received replies from 53.3 percent of non-340B hospitals and 28.6 percent of 340B hospitals. These response rates are similar to past surveys of health care providers as determined by a separate meta-analysis [117] and have resulted in sample sizes that show significant differences in acquisition costs between the two hospital categories.[118] While we applied data cleaning to exclude specific survey records with anomalous or implausible data, very few hospitals were excluded from our population, only 27 subunits that reported identical and duplicative data to their parent unit. Additionally, while we applied refinements to narrow the population of hospitals to only those who either responded to the survey or had OPPS claims for survey-relevant HCPCS codes, these refinements did not remove any hospital with relevant data from analysis. These efforts were undertaken to maintain the largest possible pool of hospitals and data to evaluate. It is our view based on efforts to sensitivity test the responses and reweight the findings that the conclusion of statistical difference in the average acquisition costs for 340B and non-340B hospitals would likely not change.

2. Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) of the Act authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).

In accordance with this authority, we propose to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program as 340B covered entity hospitals because their drug acquisition costs vary significantly from those not enrolled in that program. The significant drug acquisition cost discounts that 340B covered entity hospitals receive for 340B-acquired drugs enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we propose to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act. Therefore, for 340B drugs acquired by 340B covered entity hospitals, we propose changes to better align Medicare payment with average acquisition cost for the drug as specified in statute.

As discussed in more detail below, for drugs not acquired through the 340B Program, we propose that 340B and non-340B hospitals will continue to receive payment at a payment rate that is generally ASP plus 6 percent.

We acknowledge we could set a single payment rate for a drug for a hospital group (such as 340B hospitals) regardless of whether the drug was

[112] Hospital acquisition cost is the price paid in a business-to-business market, particularly in transactions between hospitals and wholesalers or distributors. Unlike revenue, hospital acquisition cost is measured per unit quantity.

[113] With some exaggeration, this is known in economics as the ''law of one price.'' The Chicago Price Theory textbook explains with more nuance that ''Price is sometimes easier to measure than quantity because price can be seen from a sample; just go to one of the sellers in the market—say, a grocery store—and look at their price for eggs. Quantity measurement can be more difficult—you have to ask every seller what they sold; you'd need some kind of census of sellers'' (Sonia Jaffe, Robert Minton, Casey B. Mulligan and Kevin M. Murphy, *Chicago Price Theory,* 2019, p. 48).

[114] Weighting observations by volume shares, as the CMS sample does, further reduces standard errors and further increases statistical significance.

[115] Bureau of Labor Statistics, ''Handbook of Methods: Consumer Price Index—Data Sources'' (last modified Jan. 30, 2025), *https://www.bls.gov/opub/hom/cpi/data.htm* and Bureau of Labor Statistics, ''Producer Price Index (PPI): Overview'' (last modified Mar. 16, 2023), *https://www.bls.gov/ppi/overview.htm.*

[116] As a back-of-the-envelope denominator for 100,000 CPI observations, the Federal Reserve Bank of Atlanta's 2024 Survey and Diary of Consumer Payment Choice reports that U.S. consumers made 48 payments per consumer per month on average. Multiplying 267 million adults by 48 payments per month gives approximately 12.8 billion consumer payments per month. This is a conservative comparison for item-level CPI observations because a single consumer payment, such as a grocery receipt, may cover multiple items.

[117] Vincent Maurice Meyer *et al.,* ''Global Overview of Response Rates in Patient and Health Care Professional Surveys in Surgery: A Systematic Review,'' Annals of Surgery 275, no. 1 (January 2022): e75–e81, *https://pubmed.ncbi.nlm.nih.gov/32649458/* The Meyer *et al.* meta-analysis found an average response rate of 53.3% (±24.5%) over 1,746 surveys of health care professionals.

[118] Vincent Maurice Meyer et al., ''Global Overview of Response Rates in Patient and Health Care Professional Surveys in Surgery: A Systematic Review,'' *Annuals of Surgery* 275, no. 1 (January 2022): e75–e81, *https://pubmed.ncbi.nlm.nih.gov/32649458/.*

acquired through the 340B Program, but that does not align with our intent to more appropriately align payment with acquisition costs. As such, we are only applying the reduced payment rate to drugs acquired through the 340B Program by the hospital group defined as 340B hospitals as this most appropriately aligns payment with acquisition cost of drugs of this hospital group. For non-340B drugs acquired by 340B hospitals, we propose that payment will not be adjusted. We seek comment on these proposals. Specifically, we seek comment on our proposal to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act and our proposal to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program to more appropriately align payment with the average acquisition cost for the drug.

3. Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) of the Act provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug ''as determined by the Secretary taking into account'' the survey data collected under subparagraph (D). In accordance with this authority, we propose to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. Applying a single discount factor to ASP creates a standardized payment reduction. Conversely, calculating individual acquisition costs links reimbursement directly to the exact, variable purchase prices hospitals pay for specific 340B drugs.

We considered calculating payment rates derived from individual acquisition cost amounts for 340B drugs; however, given the dynamic nature of drug pricing we concluded that it would be more appropriate to apply a single discount factor to ASP. We believe this is more appropriate as ASP is also dynamic in nature. ASP changes over time (quarter to quarter), so tying the payment amount to an average discount of ASP results in a more accurate payment amount, by quarter, than if hospitals had to wait until the next survey cycle.

Each drug HCPCS code has its own specific payment rate calculated that is unique to the drug described by the applicable HCPCS code. We would apply an average discount, calculated as described previously under V.B.9.b. and V.B.9.c.(2). of this proposed rule, to the drug specific ASP amount. This makes our proposed payment rate specific to the average acquisition cost for the drug. Applying the payment rate in this manner also allows for this average discount to apply to newly calculated ASPs as they are updated on a quarterly basis. It would not be practical to calculate a drug specific payment rate for each NDC, and each HCPCS code, based on the survey data, as the survey collected data is based on a snapshot in time and would not reflect future changes in average acquisition costs. Therefore, as drug prices change, we believe it is appropriate and reasonable to continue to update the calculated ASPs and then to reduce payments by an appropriate percentage of ASP to better align payment with the average cost of the drug.

As an alternative to establishing one aggregate discount amount based on survey data, we are considering establishing one aggregate discount amount based on 340B ceiling prices from HRSA.[119] Under this alternative, we would use HRSA's 340B ceiling price data, rather than survey data, to calculate an average discount. As described previously, when assessing the 340B ceiling price, we calculated an analogous acquisition cost margin of ASP minus 28 percent for 340B drugs, which was calculated as the difference between the 340B ceiling price for each NDC in the survey and ASPs that were volume-weighted by 340B OPPS claims data utilization during the duration of the survey. We believe this could be a reasonable alternative to our proposal, as it is based on objective data from HRSA, can be updated regularly (such as quarterly or annually) with the release of new ceiling prices and new claims utilization data, and significantly diminishes the discrepancy between Medicare payment and hospital acquisition costs for these drugs. We seek comment on this alternative to set OPPS payment for 340B acquired drugs at ASP minus 28.0 percent, per the methodology described to calculate this OPPS claims volume weighted mean margin of the 340B ceiling price from ASP. We note this figure is volume weighted using OPPS claims data for the duration of the survey, but we also solicit comment on volume weighting this average based on the claims data available for the applicable calendar year in which the policy would be effective. For example, for the CY 2027 rule, this would be volume weighting based on claims data available for that year's rule, which would be claims data from CY 2025. At the end of this section, we also provide estimated impacts of this alternative policy proposal of ASP minus 28 percent based on the 340B ceiling price data, so interested parties are aware of these impacts if CMS ultimately adopts this policy for CY 2027.

We seek comment on our proposal to apply a single discount factor to the ASP for 340B-acquired drugs in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs.

4. Add-on Payment for 340B Drugs

Under the OPPS, Medicare pays separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs may also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) of the Act authorizes, but does not require, the Secretary to make an adjustment to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Because we took a prudent approach in estimating the average acquisition costs for 340B-acquired drugs, we do not believe that it is necessary to establish an add-on for overhead and handling as we believe that a conservative estimate may already account for the costs of overhead. We also believe that hospitals will likely negotiate additional discounts that will render an additional add-on payment unnecessary. This approach also aligns with the requirement under section 1833(t)(14)(A)(iii) of the Act to pay at the average acquisition cost. Therefore, for CY 2027 and subsequent years, we propose to pay for 340B drugs acquired under the 340B Program by 340B hospitals at ASP minus 33.4 percent with no add-on payment. We solicit comment on our proposal to not include an add-on payment.

5. 340B Payment Policy for Drugs for Which ASP Is Unavailable

Section 1847A of the Act establishes the average sales price (ASP) methodology, which provides the amount payable for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Based on this, our historic policy has been to pay for most drugs at ASP plus 6 percent. There are

[119] HRSA calculates the ceiling price for each covered outpatient drug. The 340B ceiling price is the drug's average manufacturer price (AMP) minus the unit rebate amount (URA), which is a statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug. The 340B ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug.

some situations, however, where it is not possible to pay ASP because, for example, a drug is sufficiently new so there is no sales data available upon which to derive an average. In these situations, our historic policy has been to pay for the drug according to the following hierarchy: In general, if ASP information is not available, payment is based on the WAC with WAC plus 6 percent. If WAC information also is not available, then payment is based on AWP with 95 percent of AWP being paid. If AWP is not available, then payment is based on Mean Unit Cost (MUC) and if MUC is not available then payment is based on the invoice price.

Consistent with this policy, starting in CY 2027, we propose that payment for 340B drugs when ASP is unavailable mirrors CMS's historic payment policies for drugs paid under OPPS. If ASP information is not available, payment is based on the WAC, with WAC minus 33.4 percent. If WAC information also is not available, we propose a payment rate of 59.69 [120] percent of AWP. This percent was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup. Then we applied the 33.4 percent reduction WAC-similar AWP value to obtain the 59.69 percent of AWP, which is similar to either ASP minus 33.4 percent or WAC minus 33.4 percent. For 340B drugs paid based on MUC, we propose to continue to pay them at 100 percent of MUC. These MUC based payments are calculated based on hospital claims data, which already accounts for hospital acquisition costs and does not need to be discounted further. Similarly, we propose to continue to pay for invoice priced 340B drugs at the invoice amount as the invoice price amount should already reflect the 340B discount. We seek comment on this proposal.

6. Applicability

We propose to apply our proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program. This approach would establish a uniform payment policy consistent with our historic OPPS payment policy of paying the same payment rate for SCODs and non-SCODs. We note our proposal to apply this policy to separately payable drugs and biologicals that are not SCODs is a policy proposal rather than a statutory requirement. We note that the survey included both SCODs and drugs and biologicals that we have historically treated as SCODs for payment purposes. We have treated non-SCOD drugs as SCODs for payment purposes since CY 2006. We seek comment on this proposal.

The proposed payment policy would not apply to vaccines, as they are excluded from the 340B Program; drugs with transitional pass-through payment status, which are paid under 1833(t)(6)(D) of the Act; and non-opioid pain management drugs as defined under section 1833(t)(16)(G) of the Act, as we believe reducing payment for those drugs would be inconsistent with statutory instructions on payment amount for those qualifying products.

As previously described in the OMB approved PRA, CMS may continue to validate the results of this survey on a periodic basis; for example, perhaps as often as every 4 years. We seek comment on this proposal. Specifically, we seek comment on the proposal that the proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent would apply to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program, and would not apply to vaccines, drugs with transitional pass-through payment status and non-opioid pain management drug.

Additionally, as we propose to apply a single discount factor to the ASP for 340B-acquired drugs in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs, we believe it is appropriate to apply this payment adjustment using the single discount factor to existing and new drugs that are paid under the OPPS.

7. Beneficiary Copayments

An important consequence of our proposed policy is that it will reduce Medicare beneficiaries' copayments for Medicare Part B drugs. Medicare beneficiaries are liable for a copayment that is typically equal to 20 percent of the OPPS payment rate, which is currently generally ASP plus 6 percent (regardless of the 340B purchase price for the drug). As the survey demonstrates, in some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program. For example, Lupron Depot (NDC 00074–3663–03) had a mean adjusted ASP of $4,690.08 compared to an average 340B acquisition cost of $667.94, excluding outliers and responses above the 340B ceiling price, yielding an absolute margin of −$4,022.14 and a percent margin of −85.8 percent. As the drug is paid at ASP plus 6 percent, the payment rate for one package of the NDC averaged $4,971.49, of which a beneficiary would pay 20 percent, or $994.30. Therefore, a beneficiary's copay would be over $300 above the average hospital's 340B acquisition cost. During the ODACS study period, 3,544 beneficiaries had an OPPS claim for Lupron Depot, meaning that a sizeable beneficiary population is affected by these high coinsurance amounts. This is also not a small sample size aberration: 137 hospitals reported purchasing this drug through 340B (after excluding outliers and responses above the 340B ceiling price).

Additionally, sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A (i) of the Act which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. Pursuant to section 1847A(i)(5) of the Act, the IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount.

Section 11101(b) of the IRA amended section 1833(t)(8) of the Act by adding a new subparagraph (F) to modify OPPS copayments for Part B rebatable drugs. In the CY 2024 OPPS/ASC final rule with comment period, we codified the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41, which states in the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of

[120] Except for new drugs and biologicals that have not been assigned a HCPCS code. Under section 1833(t)(15) of the Act, these drugs and biologicals are required to be paid at 95 percent of AWP.

the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the outpatient prospective payment system is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under § 419.41(d) (other than application of the limitation described in paragraph § 419.41(c)(4)(i)), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply. In the CY 2025 PFS final rule, we codified policies regarding the computation of the inflation-adjusted beneficiary coinsurance, including § 427.201, which specifies that the methodology set forth in § 427.201(b) will be used to calculate the inflation-adjusted beneficiary coinsurance and associated Medicare payment percentage for Part B rebatable drugs as set forth in §§ 410.152(m), 419.41(e), and 489.30(b)(6). The methodology at § 427.201(b) ensures that coinsurance adjustments are not applied in a manner that would increase beneficiary coinsurance. For additional details on this coinsurance policy, we refer readers to the full discussion at 89 FR 98237 and 98238.

Under 1833(t)(8)(F) of the Act and current OPPS regulations at § 419.41(e), beneficiary coinsurance is adjusted for Part B rebatable drugs paid under the OPPS only where a Part B rebatable drug is paid the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act—that is, for single source drugs and biologicals, paid 106 percent of the lesser of ASP or WAC, and for biosimilar biological products, paid the amount determined under 1847A(b)(8) of the Act. Because, as proposed, separately payable, non-passthrough, 340B-acquired drugs would be paid an amount other than the amount under section 1847A(i)(3)(A)(ii)(I) of the Act, the coinsurance adjustment provisions of the Medicare Part B Inflation Rebate Program would not apply to separately payable, non-pass-through, 340B-acquired drugs under the proposed payment policy. We believe this is appropriate and consistent with the statutory intent of the Medicare Part B Inflation Rebate Program, as the coinsurance adjustment at 1847A(i)(5) of the Act is intended to reduce the coinsurance amount to equal that of 20 percent of the inflation-adjusted payment amount described at 1847A(i)(3)(C) of the Act, and we expect that the applicable coinsurance under the payment proposal for 340B-acquired drugs would likely be lower than 20 percent of such inflation-adjusted payment amount. We seek comment on the interaction between coinsurance adjustments under 1847A(i)(5) and the proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent.

We anticipate that our proposed policy to pay for separately paid drugs acquired under the 340B Program at ASP minus 33.4 percent will collectively reduce beneficiary copayments by an estimated $1.15 billion for CY 2027.

8. 340B Payment Policy Exemptions

We propose to exempt children's hospitals and PPS-exempt cancer hospitals from our proposed policy to adjust OPPS payments for drugs acquired under the 340B Program. In accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. Consequently, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2027 and subsequent years, we propose that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be exempted from the 340B payment adjustment and that these hospitals would continue to generally be paid ASP plus 6 percent for drugs. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in future rulemaking.

We note that hospitals listed under 42 CFR 419.20(b),[121] such as Critical Access Hospitals (CAHs) and Rural Emergency Hospitals (REHs), would not be subject to our proposed payment adjustment for 340B-acquired drugs.

We seek comment on our proposal to exempt children's hospitals, PPS-exempt cancer hospitals and rural SCHs from the 340B drug payment adjustment.

9. 340B Payment Policy for Drugs Furnished by Nonexcepted Off-Campus Departments of a Hospital

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and will instead be paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are

[121] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20.*

otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.'' For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

To implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the PFS as the ''applicable payment system'' that applies in most cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (90 FR 53770). These PFS rates incorporate the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting. For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729). For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician's office setting at ASP plus 6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a cost per day exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in sections V.A. and V.B. of this proposed rule, section 1847A of the Act establishes the ASP methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the WAC, and the AWP (90 FR 53682). As noted in section V.B. of this proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (90 FR 53702). Consequently, in the case of services furnished in a hospital outpatient department, Medicare has historically paid ASP plus 6 percent for separately payable Part B drugs and biologicals. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 53697 through 53766).

As a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately billable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term ''applicable payment system,'' we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately-payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As discussed previously, our proposal to adjust the payment rate for separately payable drugs and biologicals (other than vaccines, drugs on pass-through payment status and non-opioid pain management drugs) acquired under the 340B Program from ASP plus 6 percent to ASP minus 33.4 percent would apply to separately payable drugs and biologicals paid under the OPPS. Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, nonexcepted items and services furnished by nonexcepted off-campus PBDs are not covered outpatient department services and, therefore, are not payable under the OPPS. This means that, absent our inclusion of them in our proposed policy, nonexcepted off-campus PBDs would not be subject to the payment changes we propose. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment for these departments would present a

significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs, biologicals, biosimilars, and radiopharmaceuticals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. It would also undermine our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. To avoid such perverse incentives and the resulting distortions, we propose for CY 2027 and subsequent years, to pay an amount equal to ASP minus 33.4 percent, or equivalent, for drugs, biologicals, biosimilars, and radiopharmaceuticals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs.

Consistent with the approach to budget neutrality we adopted when we previously implemented a reduction for 340B acquired drugs furnished by nonexcepted off-campus PBDs (83 FR 59021) and our approach to budget neutrality for items and services provided by nonexcepted off-campus PBDs generally (83 FR 58832), these adjusted payments would not be budget neutralized. We expect that for CY 2027 this would result in savings of approximately $735 million to the Medicare Part B Trust Fund and would collectively reduce beneficiary copayments by an estimated $185 million. These beneficiary savings are included in the $1.15 billion figure in section 7. Beneficiary Copayments.

10. Billing Modifiers

To effectuate the payment adjustment for 340B-acquired drugs, we propose that, beginning January 1, 2027, providers who are not exempted from the 340B payment adjustment would report modifier ''JG'' (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug was acquired under the 340B Program. The phrase ''acquired under the 340B Program'' would include all drugs acquired under the 340B Program or Prime Vendor Program, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program would not be reported with the modifier ''JG''. For separately payable drugs (status indicator ''K''), application of modifier ''JG'' would trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 33.4 percent.

We additionally propose that, beginning January 1, 2027, for drugs or providers that are exempted from the 340B drug payment policy for CY 2027, which include pass-through drugs (SI ''G''), non-opioid treatment for pain relief drugs authorized under section 4135 of the CAA, 2023 (SI ''K1''), rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, should not report modifier ''JG''. Instead, these exempted providers should report the informational modifier ''TB'' (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier ''TB'' will facilitate the collection and tracking of 340B claims data for OPPS providers that are exempted from the payment adjustment in CY 2027. However, use of modifier ''TB'' will not trigger a payment adjustment and these providers will generally receive ASP plus 6 percent for separately payable drugs furnished in CY 2027, even if such drugs were acquired under the 340B Program.

We also propose that, beginning January 1, 2027, all providers report a distinct modifier to identify drugs and biologicals that were not acquired under the 340B Program. Specifically, we are establishing a new modifier, ''XX'' (Drug or biological not acquired under the 340B Drug Pricing Program), which we propose will be required to be reported for all separately payable drugs that were purchased outside of the 340B Program. Note, ''XX'' is a placeholder modifier code that will be updated in the CY 2027 OPPS/ASC final rule with comment period, if this policy is finalized.

The requirement to use modifier ''XX'' would apply to all providers paid under the OPPS, including excepted and non-excepted off campus provider-based departments. Reporting the modifiers ''XX'', ''JG'', or ''TB'' for applicable drugs would ensure that all drug claims are consistently categorized as either 340B-acquired or non-340B-acquired. We believe that requiring the use of modifier ''XX'' for non-340B drugs will improve the completeness and consistency of claims data, facilitate program integrity and oversight, and enhance our ability to monitor acquisition patterns across providers. The use of modifier ''XX'' would not trigger a payment adjustment and such drugs would continue to be paid at the applicable OPPS rate (generally ASP plus 6 percent for separately payable drugs) consistent with existing policy. In summary, we propose all separately paid drug claims reported under the OPPS would be reported with a modifier of either ''JG,'' ''TB,'' or ''XX'' (Table 56). We solicit comment on our proposal to require all separately paid drug claims to be reported with a modifier of either ''JG,'' ''TB,'' or ''XX''.

We believe the addition of this new modifier is consistent with the decisions that hospitals are already making (is the drug a 340B-acquired drug or a non-340B-acquired drug) when billing for these drugs. As previously mentioned, we believe requiring the use of modifier ''XX'' for non-340B drugs will improve the completeness and consistency of claims data—this requirement could even decrease burden on hospitals as it may improve the accuracy of billing, thus decreasing the need for hospitals to reprocess claims that were billed incorrectly. We request comment as to whether the addition of modifier ''XX'' would create additional burden for hospitals.

TABLE 56: DRUG CLAIM MODIFIERS FOR ENTITIES PAID UNDER THE OPPS

Hospital Type	Pass-through Drug (SI "G")	Separately Payable Drug (SI "K")	Non-Opioid Treatment for Pain Relief Drug (SI "K1")	Packaged Drug (SI "N")
340B Drugs				
340B Hospitals	TB	JG	TB	TB
Children's Hospitals	TB	TB	TB	TB
PPS-Exempt Cancer Hospitals	TB	TB	TB	TB
Rural Sole Community Hospitals	TB	TB	TB	TB
Non-340B Drugs				
All OPPS Hospitals	XX			XX Optional

Additionally, we acknowledge this billing modifier proposal would have implications for how we identify billing units of drugs acquired through the 340B Program under the Medicare Part B Drug Inflation Rebate Program. In the CY 2025 Physician Fee Schedule (PFS) final rule (89 FR 98583), we codified at § 427.303(b)(1)(iv) that we will exclude from Part B rebate calculations separately payable billing units in claim lines for institutional claims that are billed with the ''TB'' modifier for claims with dates of service on or after January 1, 2025. If we finalize our proposal to establish the requirement to use the ''JG'' modifier, in addition to the requirement to use the ''TB'' modifier, then such 340B modifier changes would necessitate changes to how we identify 340B units to exclude from Part B rebate calculations.

Consequently, we propose a conforming change at § 427.303(b)(1)(iv) to reflect proposed changes to the requirements to use billing modifiers for 340B-acquired drugs as described in section V.B.10. of this proposed rule. Specifically, to account for these billing modifier proposals, at § 427.303(b)(1)(iv), we propose to add ''or successor billing modifiers to identify 340B units''. This means, for the purposes of Part B inflation rebate calculations, we would exclude billing units acquired under the 340B Program as identified through separately payable units in claim lines billed with the ''TB'' modifier, or successor billing modifiers to identify 340B units for 340B-acquired drugs, for claims with dates of service on or after January 1, 2025. Therefore, as a matter of operations, effective January 1, 2027, CMS would identify separately payable billing units in claim lines billed with the ''TB'' modifier and proposed ''JG'' modifier. We recognize that policy amendments for the Medicare Prescription Drug Inflation Rebate Program are typically proposed in the PFS; however, we believe it is appropriate to propose an amendment to § 427.303(b)(1)(iv) in this OPPS/ASC proposed rule due to timing differences in the publication of the CY 2027 PFS proposed rule relative to the OPPS/ASC proposed rule and to ensure we are able to appropriately exclude 340B units from Part B rebate calculations starting January 1, 2027.

D. CY 2027 OPPS Payment Methodology for Non-340B Acquired Drugs Based on ODACS

CMS analyzed acquisition cost data collected through the ODACS for drugs acquired outside the 340B Program and evaluated several methodologies for estimating the relationship between hospitals' acquisition costs and ASP-based payment amounts as previously discussed in this section.

Using our preferred proposed methodology, which calculates acquisition cost margins using the geometric mean of survey-reported acquisition costs, we estimate that hospitals' acquisition costs for non-340B drugs were approximately 2.7 percent above ASP during the survey period. However, we recognize that acquisition costs reported through the survey may not fully reflect all manufacturer rebates, chargebacks, administrative fees, or other post-purchase price concessions received by hospitals, as we have not incorporated GPO discounts into the ASP plus 2.7 percent figure. Therefore, even ASP plus 2.7 percent, the reported acquisition costs, may overstate hospitals' net acquisition

costs. As a result, the estimated margin of ASP plus 2.7 percent may, in part, reflect differences in how manufacturer rebates and other retrospective discounts were reported rather than solely the underlying acquisition costs of the drugs.

The survey results for non-340B drugs exhibit greater variation than the survey results for 340B-acquired drugs. As a result, the confidence intervals for the estimated non-340B acquisition cost margins span a slightly wider range of potential values. We believe this finding is expected given the diversity of purchasing arrangements, contracting structures, and acquisition channels available to hospitals when acquiring drugs outside the 340B Program. The broader distribution of survey-reported acquisition costs suggests greater uncertainty regarding the precise average acquisition cost margin for non-340B drugs relative to the margin observed for 340B-acquired drugs.

Although the survey data suggest that hospitals' acquisition costs for non-340B drugs may be lower on average from the current payment rate of ASP plus 6 percent, the survey results are subject to slightly greater variability and may be affected by differences in the reporting of manufacturer rebates and other price concessions. Consequently, we believe the survey data should be interpreted further as we assess the need for a payment rate change for non-340B drugs.

Given the need to further consider the non-340B survey results for the reasons mentioned, including the range of reasonable acquisition cost estimates supported by the data, we are not proposing at this time to establish a survey-based payment rate for non-340B drugs. Rather, for CY 2027, after taking into account the survey results, we propose to continue paying separately payable non-340B drugs, biologicals, biosimilars, and radiopharmaceuticals as we do in CY 2026, which is generally at a rate of ASP plus 6 percent. We believe this approach appropriately considers the survey findings, including the uncertainty associated with manufacturer rebate reporting and the broader distribution of acquisition cost estimates, while maintaining stability in payment rates and allowing CMS to continue evaluating acquisition cost information obtained through its survey authority under section 1833(t)(14)(B)(iii) of the Act.

Under the same survey-based methodology proposed for determining payment for 340B-acquired drugs, such an approach for non-340B drugs would be based on the geometric mean acquisition cost estimate derived from the survey data, resulting in a payment rate of approximately ASP plus 2.7 percent. In the case of the 340B acquired drugs, the discrepancy between acquisition cost and Medicare payment is substantial and obviously apparent; however, the discrepancy between acquisition cost and Medicare payment for non-340B acquired drugs is much less significant. Therefore, we are proposing to continue paying for non-340B acquired drugs at a rate of ASP plus 6 percent. We also intend to continue evaluating the acquisition cost survey data for non-340B acquired drugs and may consider the results of this analysis in future rulemaking.

E. Summary

In summary, using the authority under section 1833(t)(14)(A)(iii)(I) of the Act, we propose for CY 2027 and subsequent years to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent and for drugs acquired outside of the 340B Program at ASP plus 6 percent. This proposal includes our previously discussed methodology used to arrive at the proposed payment rate of ASP minus 33.4 percent that we propose to apply to all drugs acquired under the 340B Program. This methodology includes using the survey volume-weighted estimate of the margin between total acquisition costs and ASP-based payments, the longstanding OPPS geometric mean trimming methodology to identify and exclude outliers and the five data refinement exclusions to remove anomalous data. Our intent is that, if finalized, this payment methodology would apply beginning January 1, 2027. We also propose that rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B Payment Policy for CY 2027 and subsequent years. To effectuate the payment adjustment for 340B-acquired drugs, we propose that, effective January 1, 2027, hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or REHs) or exempted from the 340B drug payment policy for CY 2027, would be required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug; the modifier ''TB'' for all pass-through drugs, non-opioid treatment for pain relief drugs, and 340B-acquired drugs reported by rural SCHs, children's hospitals and PPS-exempt cancer hospitals for informational purpose; and the modifier ''XX'' for all drugs that were not acquired through the 340B Program. We note these payment proposals apply to both excepted and non-excepted provider-based departments of a hospital. Finally, we propose a conforming change to § 427.303(b)(1)(iv) to ensure our process to identify 340B units for purposes of Part B inflation rebate calculations aligns with our proposed 340B modifier billing requirements.

F. Budget Neutrality

As we propose the previously defined payment adjustments through our authority under section 1833(t)(14)(A)(iii)(I) of the Act, we also propose making this adjustment in a budget neutral manner. To maintain budget neutrality within the OPPS, we have estimated that OPPS payment for 340B acquired drugs will be reduced by approximately $4.85 billion in CY 2027; however, these payments will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under the OPPS. Specifically, the redistributed dollars will increase the conversion factor for OPPS non-drug items and services by 8.44 percent for CY 2027.

We also estimated the alternative methodology previously described to pay 340B acquired drugs at ASP minus 28 percent, which is the average acquisition cost calculated from the 340B ceiling prices and volume weighted by OPPS utilization data. Through this method, we estimate that OPPS payment for 340B acquired drugs would be reduced by approximately $4.68 billion in CY 2027. Specifically, the redistributed dollars will increase the conversion factor for OPPS non-drug items and services by 8.14 percent for CY 2027.

For additional details on our proposed budget neutral implementation of this policy, please see section II.B. of this proposed rule.

F. Proposed Payment Rates for Skin Substitute APCs

In the CY 2026 OPPS/ASC final rule with comment period, we finalized a policy to separately pay for skin substitute products as incident-to supplies in the physician office, hospital outpatient, and ambulatory surgical center settings effective January 1, 2026 (90 FR 53729 through 53748). As part of this final policy, we assigned sheet-form skin substitute products to one of three clinical APCs we created based on FDA regulatory categories: APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products). For CY 2026, we set an initial payment

rate of $127.14/cm² for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products). We stated we would update the payment rates for skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. In the event ASP data was not available for a particular product, we stated we would use the outpatient hospital MUC data. If MUC was not available, we stated we would use the product's WAC or 89.6 percent of AWP if WAC was also unavailable. We finalized a policy to include all skin substitute products used across both settings as well as the combined product utilization patterns and, as soon as data was available that reflects the results of this policy, to determine a weighted average per-unit cost by group to set the payment rates for each of the three categories.

At this time, we do not believe we have sufficient data upon which to propose a revised payment rate for all three skin substitute product APCs. We also believe that updating the payment rates for CY 2027, before the impacts of the payment policy are reflected in the CY 2026 claims that will be used for CY 2028 OPPS/ASC and PFS rulemaking, could result in payment disruptions or introduce unnecessary volatility. Because updated use patterns reflecting the CY 2026 policy changes are not yet available, we propose for CY 2027 to continue the policy finalized for CY 2026 in its entirety, which includes maintaining the payment rate of $127.14/cm² for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products).

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2027 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2027. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2026 or beginning in CY 2027. The sum of the proposed CY 2027 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2027 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2026 OPPS/ASC final rule with comment period (90 FR 53766 through 53769). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (79 FR 66885 through 66888). In CY 2026, we finalized a policy to consider skin substitutes with an approved Biologics License Application (BLA) under transitional drug pass-through payment status and skin substitutes with the Food and Drug Administration (FDA) Premarket approval (PMA) or FDA 510(k) clearance continue to be evaluated under transitional device pass-through payment status. (90 FR 53636). Therefore, for CY 2027, we also propose to include an estimate of any skin substitutes and similar products with FDA PMA or FDA 510(k) clearance in our estimate of pass-through spending for devices and skin substitutes with an approved BLA under transitional drug pass-through spending for drugs and biologicals.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Consistent with current policy, we propose to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2027, and therefore our estimate of drug and biological pass-through payment for CY 2027 for this group of items is $12.2 million.

Payment for certain drugs,[122] specifically contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package non-pass-through drugs and biologicals that function as supplies when used in a diagnostic test or procedure unless a high-cost diagnostic radiopharmaceutical with a per-day cost greater than the proposed per-day

[122] In the CY 2025 OPPS/ASC final rule with comment period, we finalized the high-cost diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this proposed rule for more information regarding this policy.

threshold referenced in section II.A.3.c. of this proposed rule is used for the test or procedure. We policy-package all drugs and biologicals that function as supplies when used in a surgical procedure or for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c. of this proposed rule. Consistent with current policy, for CY 2027, we propose that policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP plus 6 percent, like other pass-through drugs and biologicals less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2027 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81774 through 81776), we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. Consistent with current policy described in section V.A.5. of this proposed rule, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2027. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in CY 2027. The sum of the CY 2027 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2027 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2027

For CY 2027, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2027, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2026 (90 FR 53767). The pass-through payment percentage limit is calculated using pass-through- spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2027, there are 15 active categories for CY 2027. The active categories are described by HCPCS codes C1605, C1606, C8000, C1735, C1736, C1737, C1738, C1739, C9610, C1740, C1741, C1742, C1607, C1608, and C1743. Based on CY 2025 Medicare hospital outpatient claims data available by the time of this proposed rule and information from the device manufacturers provided in their respective pass-through applications regarding the device cost and the projected CY 2027 OPPS utilization, we estimated the CY 2027 pass-through expenditures for each of the 15 device categories in Table 56A.[123] Therefore, we propose an estimate for the first group of devices of $177.6 million.

[123] Estimated costs are updated to reflect the Medicare hospital outpatient claims data for each HCPCS code as such data becomes available. Prior to the availability of Medicare hospital outpatient claims data, estimated costs are based on the device cost and projected CY OPPS utilization provided by the device manufacturer in the device pass-through application. As such, the estimated pass-through costs for HCPCS codes C1605, C1606, C8000, C1735, C1736, C1737, C1738, C1739, and C9610 are based on CY 2025 Medicare hospital outpatient claims data available for this proposed rule. The estimated pass-through costs for HCPCS codes C1740, C1741, C1742, C1607, C1608, and C1743 are based on information provided by the device manufacturers in the respective device pass-through applications regarding the device cost and the projected CY 2027 OPPS utilization.

TABLE 56A: ESTIMATED PASS-THROUGH EXPENDITURES FOR DEVICE CATEGORIES THAT ARE CURRENTLY ELIGIBLE AND WILL CONTINUE TO BE ELIGIBLE FOR PASS-THROUGH PAYMENT IN CY 2027

HCPCS Code	Effective Date	Pass-through Expiration Date	Estimated Pass-through Expenditures in CY 2027
C1605	07/01/2024	06/30/2027	$8.4 million
C1606	07/01/2024	06/30/2027	$0.4 thousand
C8000	10/01/2024	09/30/2027	$0.9 million
C1735	01/01/2025	12/31/2027	$6.8 million
C1736	01/01/2025	12/31/2027	$3.6 million
C1737	01/01/2025	12/31/2027	$1.4 million
C1738	01/01/2025	12/31/2027	$0.1 million
C1739	01/01/2025	12/31/2027	$0.6 million
C9610	01/01/2025	12/31/2027	$36.1 million
C1740	10/01/2025	09/30/2028	$31.7 million
C1741	10/01/2025	09/30/2028	$7.5 million
C1742	10/01/2025	09/30/2028	$0.7 million
C1607	01/01/2026	12/31/2028	$12.5 million
C1608	01/01/2026	12/31/2028	$22.4 million
C1743	04/01/2026	03/31/2029	$44.9 million

In estimating our proposed CY 2027 pass-through- spending for device categories in the second group, we included the following: (1) device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2027; (2) additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2027; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2027. For CY 2027, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, we propose to deny six CY 2027 device pass-through applications. We propose to continue device pass-through payment status for seven device pass-through applications that were granted conditional approval in CY 2027.[124] The proposed estimate of CY 2027 pass-through spending for this second group of device categories is $5.6 million.

To estimate proposed CY 2027 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2027, we propose to use the CY 2025 Medicare hospital outpatient claims data regarding their utilization, information provided in their respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2027 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged contrast agents, drugs, biologicals, radiopharmaceuticals with per-day costs at or below the packaging threshold that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2027, we estimated the pass-through payment amount as the difference between the general payment rate of ASP plus 6 percent and the payment rate for non-pass-through drugs and biologicals that would be separately paid. Because we propose to utilize a payment rate of ASP plus 6 percent for most separately payable drugs and biologicals in this proposed rule, the proposed payment rate difference between the pass-through payment amount and the non-pass-through payment amount is $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2027 pass-

[124] As discussed in section IV.A.2. of this proposed rule: the pass-through applications for MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, and WiSE® (Wireless Stimulation of the Endocardium Technology) CRT System were preliminarily approved for transitional pass-through payment under the alternative pathway effective October 1, 2025; the pass-through applications for SetPoint System and TOUCH® CMC 1 Prosthesis were preliminarily approved for transitional pass-through payment under the alternative pathway effective January 1, 2026; the pass-through application for Esprit™ BTK Everolimus Eluting was preliminarily approved for transitional pass-through payment under the alternative pathway effective April 1, 2026; and the pass-through application for TOPS™ System was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2026. Due to the timing of the preliminary approvals, the CY 2027 spending estimate for MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE®, SetPoint System, TOUCH® CMC 1 Prosthesis, and Esprit™ BTK Everolimus Eluting is included in the CY 2027 spending estimate for the first group of devices, and the CY 2027 spending estimate for the TOPS™ System is included in the CY 2027 spending estimate for the second group of devices.

through estimate the difference between payment for the policy-packaged drug or biological at ASP plus 6 percent (or wholesale acquisition cost (WAC) plus 3 or 6 percent according to the policy in section V.B.2.a. of this proposed rule, or 95 percent of average wholesale price (AWP), if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. Diagnostic radiopharmaceuticals that currently have pass-through status, but would likely be paid separately because of the policy initially established in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93953) to separately pay for high-cost diagnostic radiopharmaceuticals with per-day costs greater than the proposed per-day threshold and which we propose to continue as discussed in section II.A.3.c. of this proposed rule, are not considered to be policy-packaged and therefore are not included in this group. For this first group of policy-packaged drugs and biologicals, we estimated a pass-through spending for CY 2027 of $2.2 million.

To estimate proposed CY 2027 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2026, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2027, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2027), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2027 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2027 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2027 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2027 would be approximately $195.3 million (approximately $183.1 million for device categories and approximately $12.2 million for drugs and biologicals), which represents only 0.18 percent of total projected OPPS payments for CY 2027 (approximately $111 billion). Therefore, we estimate that pass-through spending in CY 2027 will not exceed the 2.0 percent of total projected OPPS CY 2027 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2027, we propose to continue our current clinic and emergency department (ED) hospital outpatient visit payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448 and 70449). We also propose to continue our payment policy for critical care services for CY 2027. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449 through 70453), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by excepted off-campus provider-based departments (PBDs) applies for CY 2022 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2022 and subsequent years (86 FR 63664). As stated in the CY 2018 PFS final rule (82 FR 53020 through 53024), the PFS-equivalent rate for CY 2018 and subsequent years is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid 40 percent of the OPPS rate for the clinic visit service in CY 2027.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051), we finalized a policy for CY 2023 and subsequent years that excepted off-campus PBDs (departments that bill the modifier ''PO'' on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051).

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare began paying for intensive outpatient services furnished by hospital outpatient departments, community mental health centers (CMHCs), Federally qualified health centers, and rural health clinics in addition to opioid treatment programs. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Background

1. Partial Hospitalization

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders (SUD). Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration

of the items and services provided under the plan, and the goals for treatment under the plan.

Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a CMHC, as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding PHP.

PHP policies and payment have been addressed under OPPS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes, by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP Ambulatory Payment Classification (APC) per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176). We also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 and 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70453 through 70467), we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule with comment period data with respect to hospital-based PHP providers, and renumbered the PHP APCs. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381 and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, as long as the location met all conditions of participation to the extent not waived. A hospital or CMHC could furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary was registered as an outpatient. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72247), we confirmed that these provisions applied only for the duration of the COVID–19 PHE. On May 11, 2023, the COVID–19 PHE ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 and 63666), as a result of the COVID–19 PHE, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71995), we finalized our proposal to use the latest available CY 2021 claims but use the cost information from prior to the COVID–19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs. The application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, $142.70. In addition, we clarified the payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital that would not be recognized as PHP services; however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81811), we revised the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act, as amended by section 4124(a) of Division FF of the CAA, 2023. In addition, we modified the regulations for PHP at § 410.43 to include references to SUD. In the same CY 2024 OPPS/ASC final rule with comment period, we also established separate payment rates for PHP days with 3 services and days with 4 or more services. Accordingly, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). We also finalized a policy to utilize the separate CMHC rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes three or four PHP services in a day. Lastly, we finalized several changes beginning in CY 2024 to align coding, billing, and payment between PHPs and intensive outpatient programs.

In the 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), we modified the payment rate methodology for calculation of CMHC costs for PHP. We applied the 40 percent MPFS Relativity Adjuster to the hospital-based PHP costs to determine the CMHC costs for PHP.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023, amended section 1861(ff) of the Act, establishing Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. An intensive outpatient program (IOP) is a distinct and organized program of psychiatric services for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and SUD. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. Section 1861(ff)(4) of the Act defines intensive outpatient services as the items and services described in section 1861(ff)(2) of the Act prescribed by a physician for an individual determined (not less frequently than every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in intensive outpatient services. Section 1861(ff)(4)(C) of the Act specifies that an IOP is a program furnished by a hospital to its outpatients, by a CMHC, by a Federally qualified health center (FQHC), or by a rural health clinic (RHC) as distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding IOP.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81812 through 81857), we established payment and program requirements for the IOP benefit furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC. In addition, we established Medicare Part B coverage for IOP services provided by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD).

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(4) of the Act, we finalized regulations at 42 CFR 410.44 to set forth the conditions and exclusions applicable for intensive outpatient services, and at § 424.24 to set forth the content of the certification and plan of treatment requirements for intensive outpatient services. We also revised certain existing regulations at §§ 410.2, 410.3, 410.10, 410.27, 410.150, and 419.21 to add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OPPS. Additionally, we created regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we revised § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023.

In addition, as discussed in greater detail in the following sections, we established coding, billing, and payment policies for IOP that align with the policies established for PHP provided in the same settings. Specifically, we established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively). Similar to the policy finalized for PHP, we finalized a policy to utilize the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes three or four IOP services in a day.

For IOP services provided by an RHC or FQHC, we established a three-service per day payment rate based on the same rate as APC 5861, which is the three-service hospital-based IOP rate (§ 405.2462(j)). In the CY 2025 PFS final rule, we established a four or more services per day payment rate for an IOP provided by an RHC or FQHC based on the same rate as APC 5862, which is the four or more services hospital-based IOP rate (89 FR 98017 and 98018). Information regarding payment policies for IOP services furnished by FQHCs and RHCs, including information regarding proposed CY 2027 policies for those settings, can be found in the CY 2027 PFS proposed rule, which is published elsewhere in the **Federal Register**.

Furthermore, in the CY 2024 OPPS/ASC final rule with comment period, we established a payment adjustment for IOPs provided by an OTP based on three times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)). We finalized regulations at § 410.67(d)(4)(ii) to add that the payment amount for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor (GAF) described in § 414.26. Lastly, we amended § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services is updated annually using the Medicare Economic Index described in § 405.504(d). Payment rates for IOP provided in the OTP setting are updated as part of the OTP fee schedule and are not addressed in this proposed rule.

In the 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), we modified the payment rate methodology for calculation of CMHC costs for IOP. We applied the 40 percent MPFS Relativity Adjuster to the hospital-based IOP costs to determine the CMHC costs for IOP.

B. Coding and Billing for PHP and IOP Services Under the OPPS

In the CY 2024 OPPS/ASC final rule with comment period, we finalized a billing requirement that all providers use condition code 41 to indicate that a claim is for partial hospitalization services and use condition code 92 to identify intensive outpatient claims, effective January 1, 2024. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we stated in the CY 2024 OPPS/ASC final rule with comment period that we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial hospitalization services and intensive outpatient services. The use of condition codes 41 for PHP claims and 92 for IOP claims allows us to differentiate between these services for billing purposes.

We recognize that the level of intensity of mental health services that a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits supports a smooth transition for patients when a change in the intensity of their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as individual mental health services. The full list of HCPCs codes recognized under the PHP and IOP benefits can be found in the Medicare Claims Processing internet Only Manual, Chapter 4, sections 260.1 and 261.1, respectively, and their subsections, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf.*

To qualify for payment for the IOP APC (5851, 5852, 5861, or 5862) or the PHP APC (5853, 5854, 5863, or 5864), one service provided that day must be from the Partial Hospitalization and Intensive Outpatient Primary list. We refer readers to the CY 2024 OPPS/ASC final rule with comment period for further discussion regarding our expectation that at least one of the services on the PHP and IOP Primary list will be indicated per day for patients who need the level of care offered by a PHP or IOP program. The PHP and IOP Primary List can be found in the CY 2024 OPPS/ASC final rule with comment period at 88 FR 81821.

Beginning in CY 2024, we recognized caregiver training services and Principal Illness Navigation (PIN) services as PHP and IOP services. We explained that the reported costs associated with providing such services are included when we calculate the PHP and IOP payment rates; however, these services do not count toward the determination of whether a PHP or IOP day is paid at the 3-service or 4-service rate. We refer readers to the CY 2024 OPPS/ASC final rule with comment period for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81821 and 81822), if new codes are established that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively, such codes are added to the list of codes recognized for payment for PHP or IOP through sub-regulatory guidance. We note that coding updates frequently occur outside of the standard rulemaking timeline. We adopted this sub-regulatory process to pay expeditiously when new codes are created that describe any of the services enumerated at §§ 410.43(a)(4) and 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We explained that this policy applies to new codes that are cross walked to a previously included code, or whose code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. We stated that any additional services not described at § 410.43(a)(4) or § 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94266 through 94268) and CY 2026 OPPS/ASC final rule with comment period (90 FR 53770 through 53780), we did not add any new services not described at § 410.43(a)(4) or § 410.44(a)(4) to the list of PHP and IOP services.

C. Proposed CY 2027 Payment Rates for PHP and IOP

For CY 2027, we propose to maintain the current payment rate methodology that we use for calculating PHP and IOP payment rates for hospital-based providers. It has been our longstanding policy since CY 2011 to pay separate PHP APC per diem payment rates for CMHCs and hospital-based PHPs (75 FR 71992). As we explained in the CY 2026 OPPS/ASC final rule with comment period, beginning in CY 2024, we applied this payment structure to IOP because we expected (and subsequently have observed) differences in resource use between CMHCs and hospital OPDs for the provision of both PHP and IOP services (90 FR 53777).

As finalized in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53775 and 53776), we would apply the 40 percent MPFS Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs. Specifically, we would multiply the CY 2027 rates for the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs.

1. Background

Beginning in CY 2024, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-

service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we finalized a policy to calculate payment rates using the broader OPPS data set, instead of using hospital-based PHP data only. We explained that using the broader OPPS data set allows CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we established consistent coding and payment between the PHP and IOP benefits, we considered all OPPS data for PHP days and non-PHP days that include three or more of the same service codes. We established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81829 and 81830), we noted that the standard PHP day is typically four services or more per day. We explained that we have historically provided payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient is at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment.

In the same CY 2024 OPPS/ASC final rule with comment period, we also explained that prior to CY 2024, we historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We direct the reader to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPPS/ASC proposed rule or final rule with comment period. We stated that these PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as noted earlier, we finalized a methodology for CY 2024 to calculate hospital-based PHP payment rates for three services per day and four services per day based on cost per day using the broader OPPS data set. Accordingly, we did not apply PHP-specific trims and data exclusions, but rather we applied the same trims and data exclusions consistent with the OPPS.

We stated in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81830) that while no IOP benefit existed prior to the CAA, 2023, the types of items and services included in IOP had been, and were, paid for by Medicare either as part of the PHP benefit or under the OPPS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

In addition, in the same CY 2024 OPPS/ASC final rule with comment period, we explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration the information we received from the comment solicitation to construct an appropriate data set to develop proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we stated that we believe it was appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. We explained that although PHP claims can be specifically identified, there was no specific identifier or billing code to indicate IOP services that may have been provided before CY 2024. However, we noted that hospitals have been permitted to furnish and bill for many of these services as outpatient services under the OPPS. Thus, we analyzed a broader set of data that included both PHP and non-PHP days with three or more services in order to calculate proposed payment for PHP services. To establish consistent payment between PHP and IOP, we set IOP payment rates at the same rates as PHP. We stated that the primary goal in developing the payment rate methodology for IOP and PHP services was to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years. We stated that setting the IOP payment rates equal to the PHP payment rates was appropriate because IOP was a newly established benefit, and we did not have definitive data on utilization. However, we explained that both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week, depending on the program. Therefore, we stated that we expect it would be appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81833) we established a policy of applying the 4-service day payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with four or more services. For days with three or fewer services, we apply the 3-service day payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals). As we noted in the CY 2024 OPPS/ASC final rule with comment period, we expect days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269), for beneficiaries in a PHP or IOP, we maintained the payment rate methodology finalized in the CY 2024 OPPS/ASC final rule with comment period.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 and 53775), we explained that the calculated CY 2026 geometric mean per diem cost for CMHC PHP and IOP providers would result in an inversion (that is, the

CMHC three-service geometric mean per diem costs were greater than the CMHC four-service geometric mean per diem costs). We stated that we believed the inverted geometric mean per diem costs were influenced by the small number of CMHCs that bill Medicare for PHP and IOP services, as well as CMHCs with low costs that first began billing Medicare for services in CY 2024. We remedied this cost inversion and preserved our longstanding payment policy of appropriately reflecting the observed cost differences between the CMHC and hospital settings by applying the 40 percent MPFS Relativity Adjuster to the hospital-based PHP and IOP costs to calculate the PHP and IOP payment rates for CMHCs.

2. CY 2027 Payment Rate Methodology for PHP and IOP

For CY 2027, we propose to maintain our current methodology of calculating separate rates for hospitals and CMHCs. For the four hospital-based PHP and IOP APCs (that is, APCs 5861, 5862, 5863, and 5864), we propose using the latest available cost information, from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking, and CY 2025 OPPS claims to update the payment rates. This proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section II.A.1.a. of this proposed rule.

In accordance with the methodology finalized in the CY 2024 OPPS/ASC final rule with comment period, we propose to base the payment rate for each hospital-based PHP APC on the geometric mean per diem cost for days with three services and four or more services. We propose to use the broader set of OPPS data to calculate the geometric mean costs for hospital outpatient departments, and we propose to apply the same trims and exclusions consistent with the OPPS. We also propose to set the payment rates for the hospital-based IOP APCs based on the geometric mean per diem cost for PHP days with three services and four or more services.

For the four CMHC PHP and IOP APCs (that is, APCs 5851, 5852, 5853, and 5854), we propose to calculate the CY 2027 geometric mean per diem costs based on 40 percent of the corresponding hospital-based PHP and IOP APCs (APCs 5861, 5862, 5863, and 5864, respectively), in keeping with the methodology established in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53775 and 53776). We implemented this change in methodology for calculating the four CMHC PHP and IOP APCs to avoid possible future cost inversions (that is, the cost for 3-service days being greater than the cost for 4-service days). We believe this methodology would continue to be generally appropriate for estimating CMHC costs and aligns with the methodology that is used for other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital outpatient department. For additional information on our analyses of the data used for setting the PHP and IOP payments rates for CY 2026 and application of the 40 percent MPFS Relativity Adjuster, we refer readers to sections VIII.C.2. and VIII.C.3. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 through 53779).

Lastly, we propose that if more recent hospital cost data subsequently become available after the publication of this proposed rule, we would consider using such updated data as appropriate to determine the CY 2027 payment rates for the four hospital-based PHP and IOP APCs.

Table 57 shows the proposed calculated geometric mean per diem costs for hospital-based PHP and IOP APCs, and the proposed geometric mean per diem costs for CMHC PHP and IOP APCs with application of the 40 percent MPFS Relativity Adjuster for this CY 2027 OPPS/ASC proposed rule. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this proposed rule can be found online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*[2]

TABLE 57: PROPOSED CY 2027 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2027 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$130.63
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$173.78
5853	Partial Hospitalization (3 services per day) for CMHCs	$130.63
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$173.78
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$326.57
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$434.46
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$326.57
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$434.46

D. Proposed Outlier Policy for CMHCs

For CY 2027, we propose to maintain the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar threshold according to previously established policies to include PHP and IOP services. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81834 through 81836) for more details on CMHC outlier policies, and to section II.G. of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS/ASC final rule with comment period (68 FR 63469 and 63470), we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C. of that same final rule with comment period (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082). We are not proposing any changes to the CMHC outlier percentage policy for CY 2027.

3. Cutoff Point and Percentage Payment Amount

Also described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 and 58997), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 and 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR 81835). In the CY 2024 OPPS/ASC final rule with comment period, we extended this policy to intensive outpatient services. We are not proposing any changes to the cutoff point and payment amount policy for CY 2027.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 and 58875 and 81 FR 79678 through 79680, respectively). We are not proposing any changes to the outlier reconciliation policy for CY 2027.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). Our analysis of CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated costs from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. This cap was established after detailed analysis of claims data, which showed that a cap set at 8 percent would effectively address excessive outlier payments while minimally impacting CMHCs with legitimate high-cost cases. The cap applies to each CMHC's total per diem payments, which include both the Medicare payment portion and the beneficiary cost-sharing amount. The 8 percent cap continues to be calculated and applied on a calendar year basis, with outlier payments monitored throughout the year to ensure compliance with the cap.

This outlier payment cap only affects CMHCs; it does not affect other provider types (that is, hospital-based PHPs) and is in addition to and separate from the current outlier policy and reconciliation policy in effect. We are not proposing any changes to the outlier payment cap for CY 2027.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2026, CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852) are the only APCs for which CMHCs may receive payment under the OPPS, and these APCs are for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852), it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR

63508), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), the CY 2024 OPPS/ASC final rule with comment period (88 FR 81836), the CY 2025 OPPS/ASC final rule with comment period (89 FR 94271), and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780). We are not proposing any changes to the fixed-dollar threshold policy for CY 2027.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

The Inpatient Only (IPO) list was established in rulemaking as part of the initial implementation of the Outpatient Prospective Payment System (OPPS) in 2000, pursuant to the Secretary's authority under section 1833(t)(1)(B)(i) of the Act (65 FR 18455) to determine the services covered and paid for under the OPPS. The IPO list was created to identify services excluded from payment under the OPPS by designating certain procedures as ''inpatient only'' and therefore payable only when furnished in the inpatient hospital setting under Medicare Part A (65 FR 18442). Services included on the IPO list were those determined to require inpatient care because of the invasive nature of the procedures, the underlying physical condition of the Medicare patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The creation of the IPO list was based on the premise (rooted in the practice of medicine at that time) that Medicare should not pay for procedures furnished as outpatient services when those procedures were being performed on an inpatient basis virtually all of the time for the Medicare population because performing these procedures on an outpatient basis was not safe or appropriate, and therefore not reasonable and necessary under Medicare rules (86 FR 63671; 63 FR 47571). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696). Rather, from the beginning, we have emphasized our expectation that, in every case, the physician or surgeon and hospital will exercise their professional judgment and assess the risk of the procedure or service to the individual patient, taking into account the site of service and act in that patient's best interest (65 FR 18456). We have also previously stated that for procedures that are not included on the inpatient list, we rely on the practitioner's judgment to determine on a patient-by-patient basis whether or not a particular procedure would be most appropriately performed in the inpatient setting (70 FR 68698).

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at 42 CFR 419.22(n) to state that, effective January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the 2022 OPPS/ASC final rule with comment period, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we returned most services removed from the IPO list in 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition (86 FR 63676). We also finalized our proposal to codify the following five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation at § 419.23 (86 FR 63672):

- Most outpatient departments are equipped to provide the service or procedure to the Medicare population.
- The simplest service or procedure described by the code may be performed in most outpatient departments.
- The service or procedure is related to codes that CMS has already removed from the Inpatient Only list.
- CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.
- CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure, or CMS has proposed to specify it as a covered ambulatory surgical procedure.

For CY 2023 through CY 2025, we maintained the IPO list and continued to evaluate services brought forth by interested parties for removal using the five longstanding criteria (87 FR 72004 through 72012; 88 FR 81858 through 81863; and 89 FR 94271 through 94275).

In the CY 2026 OPPS/ASC final rule with comment period, we again finalized a policy to eliminate the IPO list over the course of three years, beginning by removing 285 mostly musculoskeletal procedures for CY 2026 (90 FR 53780 through 53802). As we stated in that rule, since the creation of the IPO list, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes such as improvements in pain management, that have reduced the inpatient length of stay and the need for postoperative care following a surgical service. We also recognize that since we previously considered elimination of the IPO list in the CY 2021 OPPS/ASC final rule with comment period, there have also been other innovations in the practice of medicine; for example, innovations in infection control spurred by the COVID–19 PHE. Additionally, we believe that there are a number of safety mechanisms that will continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives (90 FR 53857). Given the significant number of services on the list and that we would establish new reimbursement rates for those services under the OPPS, we recognized that interested parties may need time to adjust to the removal of procedures from the list. Providers may need time to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS. Therefore, we finalized our proposal to transition services off the IPO list over a 3-year period (90 FR 53783). We also refer readers to the CY 2026 OPPS/ASC final rule with comment period for further discussion on operational and beneficiary considerations, including the continuation of 2-midnight exemptions for services removed from

the IPO list, effects on beneficiary cost-sharing, and implications on the 3-day stay requirement for skilled nursing facilities (90 FR 53786 through 53788). After consideration of the comments received and the issues discussed, in the CY 2026 OPPS/ASC final rule with comment period, we finalized our proposal eliminating the criteria for removing procedures from the IPO list as it was then codified at § 419.23 and amended § 419.22(n) to state that, effective on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition period, with the list eliminated in its entirety by January 1, 2029 (90 FR 53788 to 53789 and 53086; 91 FR 8384). For further discussion on the elimination of the IPO list, please refer to section IX. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780 through 53802).

B. Proposed CY 2027 Changes to IPO List

Currently, there are 1,438 services remaining on the IPO list. For CY 2027, we propose to remove approximately half of the remaining IPO services as the second phase of the elimination of the IPO list. Therefore, we propose to remove 637 services from the following clinical families: auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary. If we finalize our proposal to remove these services for CY 2027, the majority of remaining services are more complicated in nature, and we believe the services in these clinical families may require a lengthier review process and potential changes to our current APCs in order to determine an appropriate APC assignment. For example, some of the remaining procedures for removal in CY 2028 would be from the neurological family, cardiovascular family, solid organ, intestinal, and islet cell transplants and related services. We believe these services require additional considerations due to their complex clinical nature and resources required. We expect that these remaining clinical families and services would be removed from the IPO list for CY 2028, during the third and final phase of the elimination.

The clinical families proposed for the second phase of the elimination of the IPO list were selected based on stakeholder feedback and concerns regarding proper APC placement. In the CY 2026 OPPS/ASC proposed rule, we solicited comment on the order of removal of additional clinical families of services, and/or specific services, for each of the CY 2027 and CY 2028 rulemaking cycles (90 FR 33669). We received comments requesting that we wait to remove certain invasive procedures involving craniectomy, craniotomy, and/or burr holes and cardiovascular procedures until the last phase, and we stated we would take the suggestions into consideration in future rulemaking (90 FR 53788). After further consideration, we agree with the commenters that we should wait to remove these more clinically complex and unique procedures, including the neurological and cardiovascular procedures, until the final phase. We believe that the complicated nature of the services in these clinical families may require a lengthier review process and potential changes to our current APCs in order to determine an appropriate APC assignment. Additionally, the clinical families listed above and proposed for removal in CY 2027 include multiple procedures that have been previously recommended by interested parties for removal from the IPO list. Based on our review, we also believe that the procedures in these clinical families require less adjustment to existing APCs compared to those clinical families we propose to remove in CY 2028, including the neurological and cardiovascular clinical families, meaning, they have clinical similarities and resource needs similar to that of existing procedures payable under the OPPS. As these groups of services are the next most clinically similar families, they are the natural next step in the phase out of the IPO. Therefore, we propose to remove selected less-complex services in the auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary clinical families from the IPO list for CY 2027 and are maintaining the remaining clinical families for CY 2027. If we finalize our policy as proposed, we expect to address all of the remaining clinical families and their removal during CY 2028 rulemaking.

As we have previously stated, when removing a service from the IPO list, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). As stated in previous rulemaking, services that are no longer included on the IPO list are payable in either the inpatient or hospital outpatient setting subject to the general coverage rules requiring that any procedure be reasonable and necessary, and payment should be made pursuant to the otherwise applicable payment policies (86 FR 63675). We determined the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and reviewing the Medicare Severity Diagnosis Related Groups (MS–DRG) rate for the service under the IPPS. It should be noted, however, that we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting (67 FR 66740). Additionally, we are continuing to seek comments on whether we should restructure or create any new APCs or C–APCs to allow for efficient OPPS payment for services that are removed from the IPO list to account for this significant increase in services that will now be eligible for OPPS payment.

In summary, we propose to remove 637 services from the IPO list for CY 2027 as the second phase of the elimination of the IPO list. These services and their proposed status indicators and APC assignments (if applicable) are listed in the public use file titled ''Proposed Procedures for Removal from the IPO List for CY 2027'', which is available on the CMS website. The services proposed for removal from the IPO list for CY 2027 and their proposed status indicators and APC assignments (if applicable) are also included in Addendum B of this proposed rule. The complete list of codes that describe services that are proposed to be paid by Medicare in CY 2027 as Inpatient Only services is included as Addendum E to this proposed rule.

X. Nonrecurring Policy Changes

A. Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

1. Background

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of clinic visit services furnished in excepted off-campus provider-based departments (PBDs). We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and payment policies we developed to address unnecessary increases in the volume of covered outpatient department (OPD) services. Below we discuss the policy we

finalized in the CY 2019 OPPS/ASC final rule with comment period and its expanded application under the OPPS in subsequent years.

In the CY 2019 OPPS/ASC final rule with comment period, we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services. We applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). However, we phased in the application of the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted provider-based department setting over 2 years. For CY 2019, the payment reduction was phased-in by applying 50 percent of the total reduction in payment that would have applied if these departments were paid the site-specific PFS rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). We provided for a 2-year phase-in of this policy under which one-half of the total 60 percent payment reduction (a 30 percent reduction) was applied in CY 2019. These departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30 percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second year of the 2-year phase-in, we stated that we would apply the total reduction in payment that is applied if these departments (departments that bill the modifier ''PO'' on claim lines) are paid the site-specific PFS rate for the clinic visit service described by HCPCS code G0463. For CY 2020 and subsequent years, the PFS-equivalent rate was 40 percent of the proposed OPPS payment (that is, 60 percent less than the OPPS rate).

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we implemented this policy in a non-budget neutral manner. We did so to ensure that our method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs did not simply increase other unnecessary expenditures within the OPPS, thus driving different utilization-distorting decisions.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy which provided that off-campus PBDs (departments that bill the modifier ''PO'' on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2024 and subsequent years, we continued to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53448), we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services for additional services. We finalized a policy for CY 2026 and subsequent years to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a non-excepted off-campus PBD (the PFS payment rate) for any HCPCs codes assigned to the drug administration services APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines) (90 FR 53821). In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53824), we also finalized a policy which provided that off-campus PBDs (departments that bill the modifier ''PO'' on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the volume control method policy for drug administration services that applies a PFS-equivalent payment rate for the drug administration services APCs (5691–5694), when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of both policies, we refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 53802 through 53824).

We noted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53810 through 53812) that section 1833(t)(2)(F) of the Act provides authority to implement this policy. The U.S. Court of Appeals for the District of Columbia Circuit held in *American Hospital Ass'n* v. *Azar* that a service-specific, non-budget-neutral reduction of the reimbursement rate for OPD services ''qualifies as a 'method for controlling unnecessary increases in the volume of covered [outpatient] services'' under that provision. 964 F.3d 1230, 1245 (D.C. Cir. 2020) (quoting section 1833(t)(2)(F) of the Act, 42 U.S.C. 1395*l*(t)(2)(F)). The D.C. Circuit reasoned in part that ''[t]he lower the reimbursement rate for a service, the less the incentive to provide it, all else being equal[,]'' and ''[r]educing the reimbursement rate . . . is naturally suited to addressing unnecessary increases in the overall volume of a service provided by hospitals.'' *Id.* at 1241. It ultimately concluded that the policy ''falls comfortably within the plain text'' of section 1833(t)(2)(F) of the Act, *id.* at 1241, ''and 'fits the design of the statute as a whole . . . and its object and policy,'' *id.* at 1245 (quoting *Good Samaritan Hosp.* v. *Shalala,* 508 U.S. 402, 418 (1993)). We noted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53810) that we continue to believe that our interpretation of the Act is the best one, and that this policy falls well within the Act's delegation to the Secretary to ''develop a method for controlling unnecessary increases in the volume of covered OPD services''.

2. Expanding the Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments

As described in the CY 2019 OPPS/ASC final rule with comment period, we found that earlier rulemaking efforts were insufficient to control the unnecessary growth of certain covered OPD services and as a result we implemented a method to control for unnecessary growth in covered OPD services by adjusting the payment rate for clinic visits in excepted off-campus PBDs to the PFS-equivalent rate rather than the higher OPPS rate. While this regulatory change has had a positive impact, we noted in CY 2026 OPPS/ASC proposed rule that there is evidence of continued unnecessary growth in the volume of OPD services driven by site-of-service payment differentials rather than clinical need for other service families.

We continue to be concerned that beneficiaries are being driven into higher cost settings of care because of financial incentives when they could safely receive care in a lower cost setting. This creates greater financial burden both for Medicare and for

beneficiaries in the form of increased coinsurance. Volume increases that seek to take advantage of financial incentives created by payment policy rather than clinical need are unnecessary and therefore warrant policy changes to address these increases. As the D.C. Circuit explained, ''[i]t is reasonable to think that Congress . . . would have wanted the agency to avoid causing unnecessary volume growth with its own reimbursement practices.'' *Am. Hosp. Ass'n* v. *Azar,* 964 F.3d at 1245. Accordingly, for CY 2026, we finalized a policy to remove this differential for drug administration services delivered in excepted PBDs. We are continuing to study and identify services that we believe have experienced unnecessary growth in volume driven by site-of-service payment differentials rather than clinical need.

In the CY 2026 OPPS/ASC proposed and final rules, we indicated we are particularly concerned about the services within the imaging without contrast APCs (APCs 5521–5524).

Imaging without contrast services are often high-volume, low-intensity services that can be provided in OPDs or freestanding offices. In the CY 2026 OPPS/ASC proposed rule, we stated that we are concerned that these services have experienced unnecessary growth and that a volume control method may be appropriate to apply in the future (90 FR 33690). Additionally, we solicited comments on whether it might be appropriate to apply a volume control method to the imaging without contrast APCs in the future.

Many healthcare services can be performed in multiple settings. Even when there is little variation in the service provided across settings, the Federal Supplementary Medical Insurance Trust Fund and Medicare beneficiaries typically pay more when that service is performed in an OPD than when the same service is performed in a physician office. That payment differential creates an incentive for providers to shift the care of beneficiaries to an OPD rather than a physician office or ASC, even if the services can be safely performed in the physician office or an ASC. Generally, 20 percent of any increased payment is the responsibility of the beneficiary in the form of coinsurance. Taking into account that any payment differential occurs across millions of claims for a variety of services each year, this threatens to create a significant source of unnecessary spending both by Medicare beneficiaries in the form of unnecessarily high copayments and by Medicare in the form of unnecessarily high Medicare payments for services that are being performed in an OPD because of the site-of-care payment difference.

In the CY 2019 OPPS/ASC final rule with comment period, we discussed vertical consolidation and the practice of hospitals purchasing freestanding physician practices and converting the billing from the PFS to higher paying OPD visits. These conversions shift market share from freestanding physician offices to OPDs. We stated that we believed there was a correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. More favorable reimbursement for hospital-owned sites compared to physician-owned sites has been shown to encourage hospitals' acquisition of physician practices.[125] [126] Once a practice is acquired and designated as an OPD, physician services can be billed at higher hospital-based rates. This type of consolidation has been associated with higher Medicare spending and more intense treatment patterns.[127] [128] [129]

The impact of vertical integration and the increases in volume of outpatient services extends to multiple clinic families. Studies have shown that, after vertical integration, the number of imaging tests performed in hospital sites of care increased while the number of procedures performed in nonhospital sites of care decreased.[130]

Our policy in the CY 2019 OPPS/ASC final rule with comment period to pay for clinic visits in excepted off-campus PBDs at the PFS-equivalent rate addressed the financial incentive for only one type of service in one outpatient setting. However, the share of other ambulatory services billed under the OPPS has continued to increase. We built upon this policy in the CY 2026 OPPS/ASC proposed rule to address the unnecessary growth in drug administration services. Like with clinic visit and drug administration services, we believe the difference in payment between OPDs and freestanding offices creates a strong incentive for providers to shift imaging without contrast services to the higher-cost setting.

For CY 2027, we have examined the growth in imaging without contrast services provided in excepted PBDs. Imaging without contrast services are diagnostic imaging procedures that do not require the administration of contrast agents and instead rely on standard imaging modalities such as X-ray, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and dual-energy X-ray absorptiometry scans (DXA) to produce clinically meaningful images. These services are generally low- to moderate-complexity and are routinely used to evaluate a wide range of conditions, including musculoskeletal injuries, organ structure, and disease screening. Imaging without contrast services can be safely and effectively furnished in multiple settings, including freestanding physician offices and hospital OPDs, without compromising diagnostic quality or patient safety.

For example, in 2023, for transthoracic echocardiograms (HCPCS 93306), a high-volume imaging without contrast service frequently provided in OPDs and freestanding physician offices, Medicare paid 294 percent more in an OPD than in a freestanding office.[131] HCPCS code 77080, which describes a DXA scan measuring bone density at the axial skeleton (hips, pelvis, spine), is the most frequently billed imaging without contrast code in excepted PBDs. In 2025, this service had a physician office payment rate of around $30 and an OPPS payment rate of approximately $106, making the same scan more than three times as expensive in the OPD than in the physician office. Based on our claims data analysis, the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. Conversely, from 2016 through 2024, the volume of HCPCS code 77080 has only grown by 2 percent in the freestanding physician office setting. This service can be and routinely is safely performed in either setting, but there is a clear financial incentive to perform this service in excepted PBDs due to substantially higher payment in the outpatient setting compared to the physician office setting.

We estimate that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. These codes comprise the overwhelming majority of imaging without contrast services provided in excepted PBDs. From 2016 to 2025, the provision of these services grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a

[125] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830.*

[126] *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13613.*

[127] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591.*

[128] *https://www.healthaffairs.org/doi/10.377/hlthaff.2020.01183.*

[129] *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14172.*

[130] *https://pmc.ncbi.nlm.nih.gov/articles/PMC9924392/.*

[131] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

33 percent increase in spending, corresponding to approximately $126 million in additional spending in CY 2025. This growth in the volume of imaging without contrast services in excepted PBDs can largely be attributed to the financial incentive to furnish low-complexity imaging services in OPDs rather than physician offices.

We considered whether other factors, such as coding changes, updates to clinical practice guidelines, or shifts in beneficiary case mix, might explain this growth. However, we believe these alternative explanations are unlikely to account for the observed patterns. Our analysis focuses on a stable set of high-volume HCPCS codes that consistently represent the vast majority of imaging without contrast services over time, limiting the likelihood that coding changes are driving the increase. In addition, we are not aware of any broad changes in clinical guidelines during this period that would warrant substantial increases in the use of routine, low- to moderate-complexity imaging services across these modalities. Finally, although there may be some variation in beneficiary characteristics over time, the magnitude of the growth in utilization, particularly when considered alongside declining fee-for-service enrollment and relatively stable or modest volume growth in physician offices, suggests that changes in case mix are not the primary driver of growth in excepted PBDs. Taken together, these considerations support the conclusion that site-of-service payment differentials, rather than clinical or coding factors, are a principal contributor to the observed increases in volume.

We stated in the CY 2026 OPPS/ASC proposed rule that we believe that financial incentives have driven volume from the office setting to the higher paying OPD setting, creating unnecessary increases in the volume of OPD services. We also stated that we believe that this problem is pervasive and exists across a number of service families. Section 1833(t)(2)(F) of the Act directs the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services, and CMS has previously interpreted this provision to permit payment adjustments that address financial incentives contributing to such increases. Consistent with this authority, CMS may implement a volume control method for imaging without contrast services furnished in excepted off-campus PBDs, where evidence demonstrates increases in utilization and that increase is disproportionately concentrated in higher-paid hospital outpatient settings. Because these services are commonly furnished in physician offices and do not generally require hospital-level resources, higher OPPS payment rates may incentivize shifts in site of care and increased utilization that are not clinically driven. As CMS established in the CY 2019 OPPS/ASC final rule with comment period and reaffirmed in subsequent rulemaking, including the CY 2026 OPPS/ASC final rule with comment period, and as the D.C. Circuit held in *American Hospital Ass'n* v. *Azar,* 964 F.3d 1230 (D.C. Cir. 2020), aligning payment rates across settings for clinically comparable services is an appropriate ''method'' to mitigate these incentives. Accordingly, applying a PFS-equivalent payment rate to imaging without contrast services in excepted PBDs represents a reasonable approach to controlling unnecessary increases in OPD service volume.

Any time a service is provided in the higher cost OPD when it could be provided safely in the physician office but is not because of financial incentives, it potentially represents unnecessary utilization of the OPD setting. In CY 2019, we started by addressing a pervasive problem with the clinic visit provided in excepted PBDs. In that case, it was practical to address only a single code, G0463, the clinic visit. For CY 2026, we finalized a policy to address drug administration services provided at excepted PBDs. We chose to address payment for these services across the APC family, meaning all codes assigned to these APCs, as we believe this volume control method should apply to all drug administration services at excepted PBDs. For CY 2027, we again propose addressing services across an APC family.

Our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services authorizes us to address real world effects of these payment inequalities. Given these continued disparities, we believe it is necessary to further examine and refine our volume control method by identifying additional covered OPD services that we believe are being shifted to the hospital setting based on financial incentives rather than medical necessity. We conducted an analysis of imaging without contrast services paid under the OPPS and present our findings on the utilization and payment of these services in the sections below.

3. Utilization of Imaging Without Contrast Services

The high volume of imaging without contrast services and the magnitude of rate differences between the physician office and OPD settings make it a family of services likely to migrate to a higher paying setting of care. Imaging without contrast services can be performed in either physician offices or OPDs. In the OPPS, imaging without contrast services are categorized into four levels of complexity. Payments are set at a category level, called an Ambulatory Payment Classification (APC). The APCs for imaging without contrast service are 5521 (Level 1 Imaging Without Contrast), 5522 (Level 2 Imaging Without Contrast), 5523 (Level 3 Imaging Without Contrast), and (Level 4 Imaging Without Contrast) 5524. For 2026, 337 Healthcare Common Procedure Coding System (HCPCS) codes make up the four levels of the imaging without contrast APCs. Although there are 337 HCPCS codes in the four imaging without contrast APCs, we estimate that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. This trend extends to non-excepted PBDs, where 70 HCPCS codes also make up over 95 percent of claims volume. There is an approximate 90 percent overlap of the top 70 most frequently billed imaging without contrast codes in excepted and non-excepted PBDs. HCPCS codes that are similar in terms of cost and clinical attributes are placed in the same APC. All HCPCS codes in the same APC have the same OPPS payment rate. The individual HCPCS and APC assignments are available in Addendum B to this proposed rule.

We evaluated the growth in volume and spending for multiple families of APCs in OPDs across multiple years of claims data. Should commenters wish to replicate any of our analyses, the CMS website includes information about obtaining the ''Limited Data Set,'' *https://www.cms.gov/data-research/files-for-order/data-disclosures-and-data-use-agreements-duas/limited-data-set-lds* through which OPPS claims data are available for purchase. Additionally, we will make publicly available a file containing the 70 HCPCS codes that we estimate account for more than 95 percent of the volume of imaging without contrast services provided in excepted PBDs.

The PO modifier was established to identify services furnished in off-campus PBDs and became mandatory following implementation of section 603 of the Bipartisan Budget Act of 2015.

CMS finalized this requirement in the CY 2016 OPPS/ASC final rule with comment period, requiring hospitals to report the PO modifier for services provided in excepted off-campus PBDs beginning January 1, 2016. We subsequently established the PN modifier to identify services furnished in nonexcepted off-campus PBDs, which are paid under the PFS-equivalent rate rather than the full OPPS rate. Hospitals were required to begin reporting the PN modifier starting January 1, 2017. The mandatory use of the PO and PN modifiers has enabled CMS, MedPAC, and the hospital industry to track utilization patterns.

We found that there has been an increase in the volume of services paid through the imaging without contrast APCs (5521–5524) over time, which indicates that there has been migration of these services to the OPD setting. From 2016 to 2025, the volume of the 70 HCPCS codes which account for over 95 percent of imaging without contrast services provided in excepted PBDs grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a 33 percent increase in spending, corresponding to approximately $126 million in additional spending in CY 2025. This growth persisted even with the introduction of the PFS-equivalent rate for PBDs subject to section 603 of the Bipartisan Budget Act of 2015 starting in 2017. The COVID–19 Public Health Emergency (PHE) did impact utilization across the OPPS, but we have seen the volume of imaging without contrast services rebound and return to this pattern of unnecessary volume growth. Between 2016 and 2025 we have seen increases in the volume of imaging without contrast services provided in OPDs utilized per beneficiary.[132] Between 2016 and 2025, for the top 70 most frequently billed imaging without contrast HCPCs codes provided in excepted PBDs, there has been an over 67 percent increase in utilization per beneficiary. This upward trend persists despite a declining Part B FFS population. During this same time, for example, FFS enrollment decreased by approximately 17 percent, indicating that imaging services are being used more frequently on a per-beneficiary basis rather than growth being driven by enrollment.

In addition to looking at the growth in volume and spending at the APC level for imaging without contrast services provided at excepted PBDs, we also examined the growth in volume at the HCPCS code level. Analysis of HCPCS-level utilization trends from 2016 through 2025 indicates that several imaging without contrast services experienced particularly pronounced growth in volume, with increases far exceeding overall Medicare enrollment growth. Several codes experienced growth in the excepted PBDs that outpaced growth in the physician office setting.

HCPCS code 77080, which describes a DXA scan measuring bone density at the axial skeleton (hips, pelvis, spine), is the most frequently billed imaging without contrast code in excepted PBDs. In 2025, this service had a physician office payment rate of around $30 and an OPPS payment rate of approximately $106, making the same scan more than three times as expensive in the OPD compared to the physician office. Based on our claims data analysis, the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. In contrast, from 2016 to 2025, utilization of this code in the physician office setting decreased modestly, by less than half a percent. HCPCS code 71045, which describes a simple chest x-ray, was created in 2018 as part of the 2018 CPT/HCPCS code restructuring for chest radiography. In 2025, this service had a physician office payment rate of around $17 and an OPPS payment rate of approximately $88, making the same scan 417 percent more expensive in the OPD than in the physician office. Based on our claims data analysis, the volume of this service has grown by over 92 percent in excepted PBDs between 2018 and 2025. From 2018 to 2025, this code decreased in volume by 33 percent in the physician office setting.

The volume for HCPCS 71250, which describes a CT scan of the chest performed without contrast dye, increased roughly 72 percent in the excepted PBD setting between 2016 and 2025. In contrast, the physician office setting experienced a comparatively modest increase of 33 percent over the same time period. In 2025, this service has a physician office payment rate of around $83 and an OPPS payment rate of approximately $106, making the same CT scan 27 percent more expensive in the OPD than in the physician office.

Similarly, HCPCS 70551, which describes an MRI scan of the brain, including the brainstem, performed without contrast material grew by 41 percent between 2016 and 2025 at excepted PBDs. From 2016 to 2025, this code only grew by 14 percent in the physician office setting. In 2025, this service had a physician office payment rate of around $127 and an OPPS payment rate of approximately $243, making the same scan 91 percent more expensive in the OPD than in the physician office.

HCPCS 76536, which describes an ultrasound of the head and neck, had excepted PBD volume increase 48 percent from 2016 to 2025. The same code only experienced a 4 percent increase in volume in the physician office setting during the same time period. In 2025, this service had a physician office payment rate of around $82 and an OPPS payment rate of approximately $106, making the same scan 29 percent more expensive in the OPD than in the physician office.

Breast imaging services also demonstrated substantial increases, with the volume of ultrasound breast complete (HCPCS 76641) increasing 52 percent in the excepted PBD setting from 2016 to 2025. From 2016 to 2025, this code decreased in volume by 25 percent in the physician office setting. In 2025, this service had a physician office payment rate of around $66 and an OPPS payment rate of approximately $106, making the same scan 60 percent more expensive in the OPD than in the physician office.

These services are generally low- to moderate-complexity imaging procedures that can be safely performed in multiple settings, and their growth in volume in excepted PBDs suggests increased utilization intensity beyond what would be expected based solely on growth in the Medicare population. We believe that the financial incentives created by payment policy rather than clinical need are a significant factor in shifting these services to OPDs. If there was not a material difference in payment rates, we believe fewer of these services would have shifted to OPDs and the corresponding increase in Medicare payments and beneficiary cost-sharing would not have occurred.

We also examined trends across excepted and non-excepted PBDs, alongside the physician office setting. There are approximately four times as many providers billing with the PN modifier (nonexcepted PBDs) as compared to the PO modifier (excepted PBDs). This substantial difference suggests that non-excepted PBD services are distributed across a much broader provider base, while volume in excepted PBDs remains concentrated among a smaller group of providers.

Excepted PBDs continue to account for the overwhelming share of imaging without contrast volume, even as non-excepted PBDs have grown steadily in recent years. Across the highest-volume services, the gap remains substantial: in 2025, excepted PBDs furnished roughly

[132] Based on our analysis of claims data and Medicare FFS enrollment.

4 to 5 times the volume of non-excepted PBDs for key services, accounting for about 75–82 percent of total combined PBD volume. For example, excepted PBDs represent approximately 81 percent of volume for HCPCS 77080 (DXA bone density scan), 79 percent for HCPCS 71046 (chest x-ray, 2 views), 79 percent for HCPCS 93306 (complete transthoracic echocardiography), and 83 percent for HCPCS 71250 (CT thorax without contrast). In the physician office setting, by contrast, these same services show relatively stable or modest growth over time rather than rapid expansion. Importantly, these are routine imaging services that rely on widely available equipment and standardized protocols and they are clinically comparable regardless of setting, meaning they can be safely and effectively performed in physician offices, non-excepted PBDs, or excepted PBDs without meaningful differences in patient acuity or quality.

For example, in its 2023 report, MedPAC examined APCs where such potentially unnecessary payment differentials exist.[133] To identify appropriate APCs, MedPAC compared the volume of services in each APC that was provided in OPDs, ASCs, and freestanding offices over the period of 2016 through 2021, but omitted 2020 because the coronavirus pandemic affected the volume of care in ambulatory settings. If freestanding offices had the highest volume for an APC, MedPAC concluded that the services in that APC could be provided safely in freestanding offices for most beneficiaries and that beneficiaries would be able to access the services in that APC. Therefore, for those services, it would be reasonable to align the OPPS payment rates with the PFS payment rates. MedPAC found that all four of the imaging without contrast APCs had higher volume in freestanding facilities than in OPDs, indicating that these services can be safely provided to beneficiaries in a lower cost setting of care.

We believe MedPAC's analysis aligns well with the rationale CMS adopted in the CY 2019 OPPS/ASC final rule with comment period: we consider OPPS utilization potentially unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in the hospital outpatient setting because of site-of-service payment differentials.

In our review of the utilization of imaging without contrast services in excepted PBDs, we found increases in the volume of services over time, increases in the volume of services provided per beneficiary, and significant volume growth for some individual HCPCS codes within the imaging without contrast APC family. We believe that these changes represent unnecessary increases in the volume of covered OPD imaging without contrast services and, therefore, we propose to apply our volume control method to these services under section 1833(t)(2)(F) of the Act.

4. Payment for Imaging Without Contrast Services at PBDs

As discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79726), we established a Medicare PFS relativity adjuster that is applied to the OPPS rate for the billed non-excepted items and services furnished in a non-excepted off-campus PBD to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the non-excepted items and services furnished in non-excepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The PFS relativity adjuster, as discussed in the CY 2018 PFS final rule, is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). Non-excepted PBDs are required to use the modifier ''PN'' so that the PFS relativity adjuster is applied to the payment of their claim. Excepted PBDs use the modifier ''PO'' on their claims to indicate that the service was provided at an excepted off-campus PBD and that payment should generally be made at the OPPS rate.

In the CY 2019 OPPS/ASC final rule with comment period, we stated that we consider the shift of services from the physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting (83 FR 59006). To better understand the migration of services to off-campus OPDs, we analyzed claims data for imaging without contrast services to assess whether increases in volume and spending could be driven by payment incentives. We examined the top 70 most frequently billed HCPCS codes in the imaging without contrast APC family at both excepted and non-excepted off-campus PBDs. These 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services in off-campus PBDs. We found that over 90 percent of these codes in the imaging without contrast APCs were in the top 70 most frequently billed codes at both excepted and non-excepted off-campus PBDs with slight variations in the order based on volume. We therefore concluded that the majority of HCPCS codes in the imaging without contrast APCs were being billed with both the ''PO'' and ''PN'' modifiers, indicating that these imaging without contrast services were safely being provided in both excepted and non-excepted PBDs.

We also compared OPPS and PFS payment rates by using PFS payment rates for the most frequently billed imaging without contrast HCPCS codes by excepted PBDs (departments that bill the modifier ''PO'' on claim lines) and volume-weighing them to create a PFS proxy average APC payment rate for all imaging without contrast services. Using this approach, we found that, on average, OPPS payment rates for excepted off-campus PBDs are approximately 2.5 times higher than PFS rates, while non-excepted PBD rates are closely aligned with the PFS. At the APC level, PFS payments range from about 31 percent to 54 percent of OPPS payments, confirming a substantial and consistent payment differential. A similar pattern is observed for beneficiary cost-sharing, where average cost-sharing in excepted PBDs is more than double that in freestanding physician offices, while cost-sharing for services provided in non-excepted PBDs is closely aligned with cost-sharing in physician offices.

We presently believe that the differential in our payment rates has created a payment incentive that has led to unnecessary growth for the services in the imaging without contrast APCs. We consider the shift of services from the physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives. We presently believe the OPPS payment rate for the imaging without contrast APCs being several times greater than the PFS rate creates such a payment incentive and that the growth in imaging without contrast services at excepted PBDs is therefore unnecessary.

We do not believe that the imaging payment limitation established under section 5102 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171), codified at section 1848 of the Act), constrains our ability to implement a

[133] *www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

volume control method for imaging without contrast services furnished in excepted off-campus PBDs. The DRA provision applies specifically to services paid under the PFS and limits payment to the lesser of the PFS or OPPS amount, but it does not directly affect payment for services furnished in PBDs. The DRA functions as a ceiling on PFS payments, ensuring they do not exceed OPPS rates, while the PFS relativity adjuster is used to scale payments appropriately when applied in the PBD setting. As a result, using PFS-equivalent rates for imaging without contrast services in excepted PBDs aligns excepted PBD payment rates under the OPPS with payment rates for these services under the PFS and therefore would not conflict with the DRA.

5. Patient Severity and Cost of Care

In comments to the CY 2019 OPPS/ASC proposed rule and subsequent rulemaking, we heard from commenters that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. We recognize that OPDs serve unique patient populations and provide services to medically complex beneficiaries; however, we presently believe that there is no evidence to demonstrate the need for higher payment for services provided in OPDs that could also be provided in lower-cost settings. This is particularly relevant for imaging without contrast services, which are generally low- to moderate-complexity diagnostic procedures, such as standard CT, MRI, ultrasound, radiography, and bone density testing, that do not require the administration of contrast agents or the associated monitoring and infrastructure. These services can be safely and effectively furnished in multiple settings, including physician offices, without compromising quality or patient safety.

In general, despite marked differences in payment rates for a range of services, identical services are being delivered to very similar patients across physicians' offices, hospital OPDs, and ASCs.[134] [135] Moreover, a 2023 literature review found no peer-reviewed evidence that shows differences in the quality of services delivered across hospital OPDs and physicians' offices.[136] In their 2023 report, MedPAC evaluated risk scores from the CMS hierarchical condition category (CMS–HCC) risk-adjustment model to compare the medical complexity of OPD patients with patients in freestanding offices. They found that, on average, OPD patients have higher risk scores, which suggests that OPD patients are potentially more medically complex than those in physician offices. However, they also found substantial overlap in the CMS–HCC risk scores of patients in these two settings, which suggests that the difference in patient severity between settings is small. Their analysis showed that the effects of patient severity on cost of care for the aligned services is not statistically significant as the services, like imaging without contrast services, are generally of low complexity. In addition, if there is a need to bill for more complex cases, under the OPPS providers can often bill separately for additional services that a patient might need such as prolonged observation, emergency medications, or additional diagnostic testing furnished in response to a complication or change in the patient's condition during the outpatient encounter. Accordingly, we continue to believe that higher OPPS payment rates for imaging without contrast services are not justified by differences in patient complexity or resource needs and may instead contribute to unnecessary increases in utilization in higher-cost settings.

6. Impact of Unnecessary Increases in Volume on the OPPS

Our concern with unnecessary increases in the volume of imaging without contrast services is tied to the health and sustainability of the OPPS. As described in table 51 in the CY 2019 OPPS/ASC final rule with comment period, we found that the mean and median annual increases in the volume and intensity of hospital outpatient services were about 5.5 percent and 5.4 percent, respectively, from 2011 to 2019. Over that period, the estimated increase in aggregate annual hospital incurred payments through Medicare FFS Part B was $28.2 billion.[137]

More recent data indicates that this trend has persisted and accelerated. As shown in Table 58, from 2019 through 2027, hospital outpatient costs per FFS enrollee are projected to grow at a mean annual rate of approximately 7.7 percent and a median annual rate of 9.2 percent.[138] After a temporary decline in 2020, annual growth rebounded sharply to 19.7 percent in 2021. From 2022 through 2027, the projected year-over-year annual growth rates are expected to range from 4.7 percent to 9.5 percent annually. As seen in Table 59, over this period outpatient hospital spending per FFS enrollee is projected to increase from $1,738 in 2019 to $3,238 in 2027, an increase of about 86 percent.[139] This translates to an increase of approximately $35 billion in aggregate annual incurred reimbursements for hospital outpatient services between 2019 and 2027. This level of growth exceeds that observed in other categories of Part B services in dollar terms and occurs despite relatively stable or declining FFS enrollment over much of the period.

When looking at this time period it is important to note that the COVID–19 Public Health Emergency (PHE) likely contributed significantly to the increase in claims volume in 2021. During the acute phase of the pandemic in 2020, many outpatient services were delayed or deferred as beneficiaries postponed routine care and providers limited non-urgent services. As these restrictions eased in 2021, utilization rebounded sharply as providers worked through substantial backlogs of postponed services and beneficiaries returned for deferred evaluations and treatment. This pent-up demand for outpatient care likely contributed to the pronounced increase in year-over-year outpatient hospital cost growth observed in 2021.

[134] *https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf.*

[135] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

[136] *https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf.*

[137] Available in Table IV.B6. at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf.*

[138] *https://www.cms.gov/oact/tr/2025.*

[139] *https://www.cms.gov/oact/tr/2025.*

TABLE 58: GROWTH IN HOSPITAL OUTPATIENT COSTS PER FEE-FOR-SERVICE ENROLLEE[138]

Calendar Year	Percent Increase
2019	5.2
2020	-5.8
2021	19.7
2022	4.7
2023	8.4
2024	9.4
2025	9.4
2026 (Estimated)	9.2
2027 (Estimated)	9.5

Calendar Year	Outpatient Hospital Spending Per Fee-For-Service Enrollee
2019	$1,738.46
2020	$1,663.57
2021	$2,021.31
2022	$2,072.33
2023	$2,230.61
2024	$2,450.22

Taken [141] together, the sustained acceleration in per-enrollee spending and aggregate expenditures suggests that factors beyond underlying beneficiary need, such as increases in service volume and intensity, are contributing to spending growth in the hospital outpatient setting. Continued increases in the volume of imaging without contrast services raise concerns about potentially unnecessary utilization. Such trends have implications for beneficiary exposure to low-value care as well as for the financial sustainability of the OPPS.

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59018), there is evidence that increased volume and intensity of certain covered OPD services is likely driven by financial incentives to furnish services in hospitals in order to receive higher reimbursement, rather than making site-of-service decisions based on medical necessity. We continue to be concerned with the rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this Congressional purpose, the OPPS has continued to be one of the fastest growing sectors of Medicare payments out of all payment systems under Medicare Parts A and B.[142] Furthermore, we are concerned that the persisting rate of growth relative to other payment systems suggests that payment incentives, rather than patient acuity or medical necessity, continue to affect site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Our authority to implement volume control methods is an important tool in combating unnecessary OPPS utilization. We have seen success in stemming unnecessary growth in the volume of clinic visits at excepted PBDs. Since 2019, when we began phasing in our volume control method, there has been a 25 percent decrease in the volume of clinic visit services performed in excepted PBDs. Since 2023, the volume of clinic visit services at excepted PBDs has stayed relatively steady. We believe that imaging without contrast services provided at excepted PBDs are in need of similar treatment.

7. Multiple Procedure Discounts

In the CY 2009 OPPS/ASC final rule with comment period (73 FR68559 through 86569), we finalized a policy that, effective January 1, 2009, we make a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3 of this proposed rule.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);

[142] *https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf.*

• APC 8007 (MRI and MRA without Contrast Composite); and
• APC 8008 (MRI and MRA with Contrast Composite).

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (non-composite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. As discussed in section XX of this proposed rule, for CY 2027 we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology.

The multiple imaging composite APC policy reflects the efficiencies that hospitals can achieve when furnishing multiple imaging procedures within the same imaging family during a single session. A similar principle underlies the multiple procedure payment reduction (MPPR) policy for diagnostic imaging services under the PFS. Under the MPPR policy, when multiple diagnostic imaging procedures are furnished to the same patient in the same session, payment for the technical component of the subsequent procedures is reduced to reflect efficiencies associated with the preparation of the patient, positioning, and other clinical and administrative activities that do not need to be repeated for each additional imaging procedure. Both the OPPS multiple imaging composite APC policy and the PFS MPPR policy recognize that furnishing multiple imaging services during the same encounter generally requires fewer resources than furnishing those services separately. Consistent with other services furnished in non-excepted PBDs, when multiple imaging procedures are performed at a non-excepted PBD and paid through one of the multiple imaging composite APCs, providers are required to report modifier ''PN,'' and the PFS relativity adjuster is applied to the composite APC payment.

As discussed later in this section, we propose to apply our volume control methodology to the imaging without contrast APCs (5521–5524). We believe it is also appropriate to apply the volume control methodology to APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite). APCs 8004, 8005, and 8007 are comprised of HCPCS codes assigned to the imaging without contrast APCs that would be subject to the volume control methodology when paid separately. In other words, the underlying imaging without contrast services that qualify a claim for payment under APCs 8004, 8005, and 8007 are the same imaging procedures for which we propose to apply the volume control methodology under the standard APC payment structure.

Accordingly, excluding APCs 8004, 8005, and 8007 from the volume control methodology would result in different payment treatment for the same underlying imaging procedures based solely on whether those procedures were paid separately or through a multiple imaging composite APC. We do not believe such differential treatment would be appropriate. Moreover, because APCs 8004, 8005, and 8007 are comprised of HCPCS codes assigned to the imaging without contrast APCs that would be subject to the volume control methodology when paid separately, excluding these composite APCs would allow a portion of the same imaging services that contribute to the volume concerns identified above to be paid outside the volume control methodology when furnished in excepted PBDs. Further, because these composite APCs are already subject to the PFS relativity adjuster when furnished at non-excepted PBDs, excluding them from the volume control methodology in excepted PBDs could create inconsistent payment incentives across settings and undermine the effectiveness of the volume control methodology. Therefore, we propose to apply the volume control methodology to APCs 8004, 8005, and 8007.

8. Payment for Imaging Without Contrast Services for CY 2027 and Subsequent Years

As we stated in the CY 2019 OPPS/ASC final rule with comment period, we consider the shift of services from the physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives (83 FR 59006). We believe the increase in the volume of imaging without contrast services is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could generally be safely provided in a lower cost setting, we believe that the growth in imaging without contrast services paid under the OPPS is unnecessary. Further, we believe that paying for imaging without contrast services provided at excepted off-campus PBDs at the PFS-equivalent rate could be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. We believe this method will control unnecessary volume increases both in terms of the number of covered OPD services furnished and costs associated with those services.

Therefore, given the unnecessary increases in the volume of imaging without contrast services in hospital OPDs, we propose to apply the PFS-equivalent payment rate to HCPCS codes assigned to the imaging without contrast APCs and to services paid through APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite) when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill modifier ''PO'' on claim lines). Under our authority in section 1833(t)(2)(F) of the Act, we would implement this proposal by applying an amount equal to the site-specific PFS payment rate for non-excepted items and services furnished by a non-excepted off-campus PBD (the PFS-equivalent payment rate). Table 60 shows the specific APCs that we would identify for this proposal, which are APCs 5521 through 5524, 8004, 8005, and 8007. Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier ''PN'') already receive a PFS-equivalent payment rate for any HCPCS codes assigned to the imaging without contrast APCs.

TABLE 60: PROPOSED NEW APCS PAID THE PFS-EQUIVALENT RATE FOR SERVICES PROVIDED AT EXCEPTED OFF-CAMPUS PBDS FOR CY 2027

APC	APC Description
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
8004	Ultrasound Composite
8005	CT and CTA without Contrast Composite
8007	MRI and MRA without Contrast Composite

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we finalized our method to address the unnecessary increases in utilization of clinic visits in the OPD setting in a non-budget neutral manner. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53448), we likewise finalized an expansion of our method to address the unnecessary increases in utilization of drug administration services in the OPD setting in a non-budget neutral manner. For CY 2027, we propose to implement this proposed method to address the unnecessary increases in utilization of imaging without contrast services in the OPD setting in a non-budget neutral manner. We continue to believe that, while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled ''Periodic review,'' provides, in part, that the Secretary must annually review and revise the groups, ''the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors'' (emphasis added). Section 1833(t)(9)(B) of the Act, titled ''Budget neutrality adjustment'' provides that if ''the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made'' (emphasis added). However, a volume-control method under section 1833(t)(2)(F) of the Act is not an ''adjustment'' under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an ''adjustment.'' Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those subparagraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in subparagraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent* year. We therefore continue to interpret this provision to mean that the Secretary can implement a volume control method under section 1833(t)(2)(F) of the Act in a non-budget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method (see 83 FR 59009).

We stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59010) that we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613). We believe that concern applies to imaging without contrast services just the same. The estimated payment impact for various provider classifications is displayed in Table 88: Estimated Impact of the Proposed CY 2027 Update to the ASC Payment System on Aggregate CY 2026 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group of this proposed rule. For CY 2027, the estimated savings are $260 million, with $190 million of the savings accruing to Medicare, and $70 million saved by Medicare beneficiaries in the form of reduced beneficiary coinsurance. And beginning in 2028, the savings from this proposed policy begin to flow into the baseline for Medicare Advantage rates, thus resulting in a significant increase in savings in subsequent years. For 2027, the Medicare Advantage rates have already been calculated at the time of this proposed rule and thus the 2027 Medicare Advantage rates are not impacted by this proposed policy. From 2027–2036 we estimate that this policy will lower net Part B spending by $7.2 billion. To effectively establish a method for controlling the unnecessary growth in the volume of imaging without contrast services furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a non-budget neutral manner. The impact associated with this proposal is further described in section XXVI. of this proposed rule.

While we are refining our method to control for unnecessary increases in the volume of hospital OPD services, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. We solicit public comments on other ways or other services for which we should exercise the Secretary's statutory

authority under section 1833(t)(2)(F) of the Act.

9. Exemption for Rural Sole Community Hospitals

As stated above, we propose to expand our method to control unnecessary increases in the volume of covered OPD services by paying a PFS-equivalent payment rate for imaging without contrast services furnished in excepted off-campus PBDs. We believe that this policy is an appropriate method for controlling unnecessary volume of imaging without contrast services in excepted off-campus PBDs because beneficiaries can generally safely receive these same services in a lower cost setting but instead may receive care in a higher cost setting due to payment incentives. In these cases, we maintain that, similar to the clinic visit volume control policy established in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the drug administration volume control policy established in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53806 through 53821), to the extent similar services can be safely provided in more than one setting, we do not believe it is appropriate for the Medicare program to pay more for these services in one setting than another. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the physician's office setting to the hospital OPD.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53821 through 53824), we finalized exemptions to our clinic visit and drug administration volume control policies for PBDs of rural SCHs. Under these exemptions, we pay the full OPPS payment rate, rather than the PFS-equivalent rate, when the clinic visit or drug administration service is furnished in excepted PBDs of rural SCHs. In those rules, we explained that rural SCHs have historically received special payment treatment to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. Because we propose a volume control payment policy for imaging without contrast services, we have additionally considered whether a similar policy for rural SCHs or other provider types would be appropriate.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established several special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers five statutory hospital payment designations in which rural or isolated hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital (CAH),[143] Sole Community Hospital (SCH),[144] Rural Emergency Hospital (REH),[145] or Medicare Dependent Hospital [146]—each of which has different eligibility criteria and payment methodologies. With the exception of CAHs, rural hospitals may also qualify as Low Volume Hospitals [147] and Rural Referral Centers (RRCs),[148] which qualify these hospitals for additional payments or exemptions. Not all rural or isolated hospitals receive special payment treatment under the OPPS. For instance, CAHs are not paid under the OPPS and are reimbursed at 101 percent of reasonable costs for outpatient services.

Rural SCHs are a hospital type that has received special payment treatment under the OPPS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary, by January 1, 2006, to provide for an appropriate adjustment under subparagraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A) of the Act, that the costs to rural hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in section II.E. of this proposed rule, for CY 2027 we propose to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

As noted above, in the CY 2023 OPPS/ASC final rule with comment period, we finalized an exemption for clinic visits to our policy to pay the PFS-equivalent rate for the clinic visit service at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were generally supportive of this proposal and noted that rural SCHs are typically the chief, if not sole, source of community outpatient care for rural residents and stated that this exemption would be vital to ensuring continued access to the care they need. Some commenters stated that the exemption should be extended to other types of hospitals, including urban SCHs. In that rule, we explained that our analysis did not find that urban SCHs had the additional resource costs for covered OPD services that rural SCHs have and only finalized applying the clinic visit policy exemption to rural SCHs (87 FR 72049).

Similarly, in the CY 2026 OPPS/ASC final rule with comment period, we finalized an exemption for rural SCHs to our policy to pay the PFS-equivalent rate for drug administration services at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were again generally supportive of the proposal and emphasized that rural SCHs have higher costs and are important for access in rural areas. Some commenters suggested extending the exemption to other types of hospitals such as urban SCHs, Medicare Dependent Hospitals (MDHs), urban and rural safety-net hospitals, REHs, FQHCs, and all rural hospitals. However, because our historical analysis did not demonstrate that these hospitals had the additional resource costs that rural SCHs do, we did not finalize any exemptions beyond our exception for rural SCHs (90 FR 53823).

b. Exemption to Volume Control Payment Policy for Imaging Without Contrast Services Furnished in Off-Campus Provider-Based Departments of Rural SCHs

Earlier in this section, where we propose the volume control method policy for imaging without contrast services, we state that to the extent there are lower-cost sites of service available beneficiaries and the physicians treating them should be able to choose the

[143] 42 CFR 485.601 through 485.647.

[144] 42 CFR 412.92.

[145] 42 CFR 419.91.

[146] 42 CFR 412.108.

[147] 42 CFR 412.101.

[148] 42 CFR 412.96.

appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons. However, as we have previously noted, many rural providers, and rural SCHs in particular, are often the only source of care in their communities,[149] which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas likely further drives utilization to off-campus PBDs in areas where rural SCHs are located.

As with clinic visits and drug administration services, we do not believe that rural SCH site-of-service decisions for imaging without contrast services are being driven by differences in payment rates. As we have previously observed, rural areas often experience lower availability of health care professionals and hospitals than urban areas.[150] Hospital closures in rural communities are associated with lower access to health care and worse health outcomes.[151] Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries from being admitted as an inpatient because beneficiaries in rural settings face unique challenges that impact their health. In the CY 2023 OPPS/ASC final rule with comment period, we explained that we believe that exempting rural SCHs from the clinic visit policy would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments (87 FR 72049). We extended this exemption to drug administration in the CY 2026 OPPS/ASC final rule with comment period on the same basis (90 FR 53822), and we propose to extend it to our proposed imaging without contrast policy for similar reasons. Specifically, we propose to exempt rural SCHs from payment of the site-specific PFS-equivalent payment for imaging without contrast services, as described by APCs 5521 through 5524, 8004, 8005, and 8007, when furnished at an off-campus PBD exempted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). Under this proposed policy, a rural SCH would continue to bill services in APCs 5521 through 5524, 8004, 8005, and 8007 with the ''PO'' modifier for CY 2027 and the payment rate for such services would continue to be the full OPPS payment without the PFS relativity adjuster.

This exemption, should it be finalized, would result in higher payments to excepted off-campus PBDs of rural SCHs compared to if it were not finalized and rural SCHs were subject to the proposed volume control method. By exempting rural SCHs, the Medicare payments for these services would remain at the OPPS level. We note, however, that these figures do not represent increases in costs to Medicare or the beneficiaries above the current policy, as our proposed exemption would maintain current payment rates at excepted off-campus PBDs of rural SCHs of 107.1 percent of the OPPS payment rate for these services. These figures are solely for the purpose of comparing potential savings should we implement a method to control unnecessary volume in imaging without contrast services without such an exemption. We invite comments on all aspects of the proposed exemption for rural SCHs from the method to control unnecessary volume of imaging without contrast services. Specifically, we request comments on whether such an exemption is appropriate for rural SCHs; what the impact on SCHs would be, should we finalize the method without an exemption for rural SCHs; and whether we should consider any other hospital types for an exemption to any of the three policies to control unnecessary volume of outpatient services at off-campus PBDs. Additionally, we request comments on whether the current exemptions for rural SCHs from the method to control unnecessary volume of clinic visit and drug administration services remain appropriate

B. OPPS Payments for SaMS Diagnostic Services

1. Payment for Software as a Medical Service (SaMS)

In recent years, there have been rapid developments in the use of software-based technologies with novel functionalities, including artificial intelligence, to support clinical decision-making in the outpatient and physician office settings. New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), is becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients, relying on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment planning of a patient's condition. In previous rulemaking, we have referred to these algorithm-driven services that assist practitioners in making clinical assessments or diagnoses as Software as a Service (SaaS). Some of the software functions that are used in these services are FDA-regulated medical devices. Unlike prescription digital therapeutics (PDTs), for example PDTs that provide cognitive behavioral therapy to treat substance disorders or chronic insomnia, SaaS technologies do not currently treat illnesses or patient injuries. SaaS is also separate from remote patient monitoring (RPM) and remote therapeutic monitoring (RTM), which are digital healthcare tools for tracking patient data outside traditional office settings (90 FR 49394). For CY 2027, we propose a change in terminology. We now understand that in other industries, the existing SaaS terminology is used for general cloud-based computing service models outside of a health care context, which may cause confusion as we are using it to describe specific services that provide a medical function for purposes of OPPS/ASC Medicare payment policy. To dispel any ambiguity and clarify that distinction, we propose to change our terminology from SaaS to Software as a Medical Service (SaMS) to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. We welcome public comments on the proposed change in terminology.

CMS has been evaluating how to develop a comprehensive and consistent approach to SaMS payment for several years with the novel and evolving nature of these technologies. We have sought public input through two comment solicitations (87 FR 72035 through 87 FR 72036, 89 FR 94129 through 89 FR 94131) and expressed our objective to seek a payment strategy that aligns with our agency's mission to increase quality, improve health, reduce costs, and strengthen the healthcare system. However, questions remain regarding how best to structure payment for these services. One challenge is that current Medicare Part B payment systems for SaMS, including in the OPPS, are primarily designed to pay for services that rely on material resources,

[149] *https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf.*

[150] *https://www.gao.gov/assets/gao-21-93.pdf.*

[151] Mills CA, Yeager VA, Unroe KT, Holmes A, Blackburn J. The impact of rural general hospital closures on communities—A systematic review of the literature. *J Rural Health.* 2024; 40:238–248. *https://doi.org/10.1111/jrh.12810.*

rather than technologies whose value is driven by proprietary algorithms and scalable, non-material costs. This creates difficulties in establishing appropriate valuation methodologies, as the current cost-based system often offers only limited transparency into underlying costs and may not effectively constrain pricing. Another challenge is determining how to account for the various ways in which these technologies are acquired and billed by hospital OPDs, particularly in cases with subscription- or license-based arrangements, as well as per-use or ''per-click'' fees, which raises concerns regarding program integrity.

As coding for SaMS continues to rapidly increase and technologies evolve, establishing a consistent and timely payment methodology for these services is a priority. New SaMS technologies are continuing to be introduced to the market, each often accompanied by unique CPT codes reflecting their proprietary algorithms or specific characteristics. Interested parties are frequently seeking Medicare payment and coding for SaMS technologies through the new technology APC process or requesting clinical APC assignments. As a result, CMS is continuously assessing and evaluating payment for SaMS through different pathways. As we consider this policy, we want to ensure that we are moving toward a more standardized approach that reduces payment rate variation across similar technologies.

Given the growing need for a comprehensive and tailored payment methodology, as we work to gather additional data to better understand and more fully address the inherent payment challenges in this area, we propose an interim payment policy for SaMS for CY 2027 while we examine a range of approaches to payment for these kinds of technologies. Specifically, we propose to assign SaMS technologies to new technology APCs for CY 2027. We propose to designate 36 HCPCS codes as SaMS services and reassign the proposed designated SaMS services that are currently paid separately (assigned to status indicator ''S'') under clinical APCs, to new technology APCs that closely align with their current CY 2026 payment rates. We propose to assign the separately paid SaMS technologies to new technology APCs because we believe that the existing clinical APC structure does not adequately accommodate SaMS. We believe that the new technology APCs are more appropriate to accommodate SaMS on a temporary basis, as there have historically been placements under the OPPS that allow us to provide consistent payment for new procedures that are not yet reflected in our claims data or for which we lack sufficient clinical information and cost data until we can identify an appropriate clinical APC. In certain circumstances, we have also assigned some services to new technology APCs through rulemaking, even when they have not met the specific regulatory criteria (66 FR 59897 through 59903) or have not applied for new technology APC assignment through the subregulatory process. For example, we have assigned certain services to new technology APCs in special cases where an appropriate clinical APC to which to assign the service does not exist. In the CY 2026 OPPS/ASC final rule with comment period, we maintained the new technology APC assignment for HCPCS codes G2082 and G2083 because we did not believe there was an appropriate clinical APC to which to assign the service (90 FR 53551). This proposed approach of assigning SaMS services to the same APC series would allow CMS to take the first step towards standardization and applying a consistent payment methodology across these services as we consider more comprehensive long-term approaches, including those that may better align payment with clinical outcomes.

We also believe it is important to distinguish SaMS technologies from other services that are assigned to new technology APCs because not all new services assigned to new technology APCs are SaMS technologies. Therefore, we propose to create a new status indicator under OPPS specifically for SaMS technologies. For CY 2027, we propose to create status indicator ''O1'' (Software as a Medical Service, Paid under OPPS; separate APC payment) and assign all services that we propose to designate as SaMS to status indicator ''O1.'' Functionally, we propose for status indicator ''O1'' to have the same payment specifications as status indicator ''S,'' to allow for separate payment. We request public comment on this proposal. We also request public comment regarding whether a new status indicator with the same specification as status indicator ''T'' (Procedure or service subject to multiple procedure discounting) would provide more appropriate payment for these services while addressing any potential program integrity concerns.

For CY 2027, we propose to designate the HCPCS codes listed in Table 61 as SaMS technologies. Of these, we propose to assign 21 HCPCS codes to new technology APCs from clinical APCs, maintaining approximate payment rate continuity with CY 2026 payment, and status indicator ''O1''. Table 61 provides the list of HCPCS codes and proposed new technology APC and status indicator assignments for CY 2027. For SaMS that are already assigned to new technology APCs for CY 2026, we propose to continue to assign these services to new technology APCs for CY 2027 while proposing to update the status indicator assignment to ''O1'' to designate these technologies as SaMS. We refer readers to section III.C. of this proposed rule for a discussion on our proposals for SaMS technologies that are currently assigned to new technology APCs for CY 2026.

We note that there are a small number of technologies we consider to be SaMS that are currently paid under the OPPS and assigned to an OPPS status indicator of ''Q1'' (STV-Packaged Codes; Paid under OPPS), indicating that the service is conditionally packaged. Services assigned to an OPPS status indicator of ''Q1'' will receive packaged payment when furnished with a significant procedure but will be separately paid when the service appears on the claim without a significant procedure. Because services assigned to new technology APCs are exempt from C–APC packaging policies, we do not believe it would be appropriate to propose to assign SaMS HCPCS codes that are currently conditionally packaged for CY 2026 to new technology APCs with status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) to indicate separate payment. As an alternative, we considered unconditionally packaging SaMS services that are currently assigned to status indicator ''Q1'' by proposing to assign the services a status indicator of ''N'' (Items and Services Packaged into APC Rates). However, we believe proposing to unconditionally package payment for CY 2027 for SaMS technologies that are currently conditionally packaged under the OPPS may result in interruptions to patient access. Given that we intend for this policy to be a first step towards more comprehensive payment policy changes and seek to minimize disruption, we believe it is more appropriate to propose to maintain the clinical APC and status indicator assignments for these codes. Therefore, for CY 2027, we propose to maintain the clinical APC and status indicator assignments for SaMS that are currently conditionally packaged under the OPPS.

Similarly, there are other HCPCS codes that describe SaMS that are assigned to status indicator ''E1'' (Items, codes, and services not covered by any Medicare outpatient benefit category; statutorily excluded; not reasonable and

necessary), status indicator ''N'' (Items or services packaged into APC rates), or status indicator ''M'' (Items and services not billable to the FI or MAC). Since these are not separately paid services under the OPPS for CY 2026, for CY 2027, we propose to maintain the OPPS status indicators to which they are currently assigned.

The various SaMS HCPCS codes that are impacted by our proposals in this section are listed in Table 61. Table 61 provides the current APC assignments, and the proposed CY 2027 APC and status indicator assignments for codes we propose to designate as SaMS services and that are currently assigned to clinical APCs or are not separately paid under the OPPS for CY 2026. We refer readers to section III.C. of this proposed rule for a discussion on the proposed CY 2027 payment rates for SaMS codes that are currently assigned to new technology APCs for CY 2026. In addition, we refer readers to Addendum B for proposed CY 2027 OPPS payment rates and status indicators for HCPCS codes that we propose to designate as SaMS. We request comment on our proposals, including the list of HCPCS codes we propose to designate as SaMS and that we propose to reassign to new technology APCs for CY 2027, including whether there are any additional HCPCS codes we should consider.

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TABLE 61: PROPOSED NEW TECHNOLOGY APC AND SI ASSIGNMENTS FOR PROPOSED SAMS HCPCS CODES FOR CY 2027

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	APC 5732 (Level 2 Minor Procedures), S	APC 1502 (New Technology - Level 2 ($51 - $100)), O1
0932T	Noninvasive detection of heart failure derived from augmentative analysis of an echocardiogram that demonstrated preserved ejection fraction, with interpretation and report by a physician or other qualified health care professional	APC 5743 (Level 3 Electronic Analysis of Devices), S	APC 1505 (New Technology - Level 5 ($301 - $400)), O1
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data	APC 5731 (Level 1 Minor Procedures), S	APC 1493 (New Technology - Level 1C ($21-$30)), O1
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0615T	Automated analysis of binocular eye movements without spatial calibration, including disconjugacy, saccades, and pupillary dynamics for the assessment of concussion, with interpretation and report	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0712T	Noninvasive arterial plaque analysis using software processing of data from noncoronary computerized tomography angiography; quantification of the structure and composition of the vessel wall and assessment for lipid-rich necrotic core plaque to assess atherosclerotic plaque stability	APC 5722 (Level 2 Diagnostic Tests and Related Services), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0731T	Augmentative AI-based facial phenotype analysis with report	APC 5733 (Level 3 Minor Procedures), S	APC 1502 (New Technology - Level 2 ($51 - $100)), O1

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
0865T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the brain during the same session	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0866T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion detection, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the brain (List separately in addition to code for primary procedure)	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 ($801 - $900)), O1

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
0992T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat without concurrent computed tomography (CT) scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
0993T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat with concurrent computed tomography scan of the heart, and including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 ($201 - $300)), O1
C8001	3D anatomical segmentation imaging for preoperative planning, data preparation and transmission, obtained from previous diagnostic computed tomographic or magnetic resonance examination of the same anatomy	APC 5721 (Level 1 Diagnostic Tests and Related Services), S	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
C9793	3d predictive model generation for pre-planning of a cardiac procedure, using data from cardiac computed tomographic angiography and/or magnetic resonance imaging with report	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 ($801 - $900)), O1
G0183	Quantitative software measurements of cardiac volume, cardiac chambers volumes and left ventricular wall mass derived from CT scan(s) data of the chest/heart (with or without contrast)	APC 5521 (Level 1 Imaging without Contrast), S	APC 1502 (New Technology - Level 2 ($51 - $100)), O1
G0566	3D radiodensity-value bone imaging, algorithm derived, from previous magnetic resonance examination of the same anatomy	APC 5721 (Level 1 Diagnostic Tests and Related Services), S	APC 1503 (New Technology - Level 3 ($101 - $200)), O1
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	APC 5733 (Level 3 Minor Procedures), Q1	APC 5733 (Level 3 Minor Procedures), Q1
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	APC 5732 (Level 2 Minor Procedures), Q1	APC 5732 (Level 2 Minor Procedures), Q1

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device	APC 5734 (Level 4 Minor Procedures), Q1	APC 5734 (Level 4 Minor Procedures), Q1
0904T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; tracing only	APC 5733 (Level 3 Minor Procedures), Q1	APC 5733 (Level 3 Minor Procedures), Q1
0944T	3D contour stimulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation.	APC 5523 (Level 3 Imaging without Contrast), Q1	APC 5523 (Level 3 Imaging without Contrast), Q1
0557T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report	N/A, M	N/A, M
0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission	N/A, N	N/A, N
0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report	N/A, M	N/A, M
0899T	Noninvasive determination of absolute quantitation of myocardial blood flow (AQMBF), derived from augmentative algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	N/A, E1	N/A, E1
0900T	Noninvasive estimate of absolute quantitation of myocardial blood flow (AQMBF), derived from assistive algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	N/A, E1	N/A, E1
0903T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; with interpretation and report	N/A, M	N/A, M

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0905T	Electrocardiogram, algorithmically generated 12-lead ecg from a reduced-lead ecg; interpretation and report only	N/A, M	N/A, M
C8937	Computer-aided detection, including computer algorithm analysis of breast mri image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	N/A, N	N/A, N
0174T	Computer-aided detection (cad) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (list separately in addition to code for primary procedure)	N/A, N	N/A, N
0175T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation	N/A, N	N/A, N

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2. SaMS Analyses Performed on Laboratory Tests

In recent years, we have seen an increase in laboratory tests that combine laboratory analyses, such as genomic sequencing or immunoassays, with computer algorithms to produce a clinical test result. The AMA CPT Editorial Panel created a category called Multi-Analyte Assays with Algorithmic Analysis, to categorize test codes that combined laboratory analyses with computer algorithms to generate clinical information. More recently, however, we are seeing the development of distinct algorithmic analyses alone.

For example, when the genomic sequencing of an individual is performed, this sequencing will likely only need to be performed once. However, once the genomic sequence has been generated, the subsequent algorithmic analyses of that sequence data can be performed an infinite number of times to produce a wide range of results and/or diagnostic or risk-related information. These secondary analyses of original genomic sequences can be proprietary and unique to a single laboratory, but could also be conducted at a range of settings. For purposes of this proposal, we are referring to subsequent stand-alone algorithmic analyses that are separate from a CLIA certified laboratory's examination of human material, as defined by 42 CFR 493.21, as ''SaMS laboratory analyses performed on laboratory tests ''.

Currently, certain SaMS analyses performed on laboratory tests are treated as clinical diagnostic laboratory tests (CDLTs) and paid under the Clinical Laboratory Fee Schedule (CLFS). Section 1861(s) of the Act specifies items and services included as ''medical and other health services'' under Part B, including diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests as described in section 1861(s)(3) of the Act. Section 1861(s)(17) of the Act states that no diagnostic tests performed in any laboratory shall be included within paragraph (3) unless such laboratory meets CLIA certification requirements under section 353 of the Public Health Service Act, among other requirements. Sections 1833(h) and 1834A of the Act and the implementing regulations at 42 CFR part 414, subpart G, set forth the CLFS ratesetting methodologies for CDLTs. We do not believe it is appropriate to consider these secondary algorithmic analyses to be CDLTs or establish CLFS payment rates for these analyses because these secondary algorithmic analyses do not require laboratory services or entities, regulated by CLIA, to perform them. Referring to the example above, while an individual's genomic sequence must be performed by a CLIA certified laboratory entity to allow for Medicare payment under the CLFS, the subsequent algorithmic analyses of the sequence data as part of the SaMS analyses performed on laboratory tests can be performed by any non-regulated entity with the computer software needed to perform the analyses. Our position is that the secondary analyses are ''other diagnostic tests'' under section 1861(s)(3) of the Act as opposed to ''diagnostic laboratory tests.'' As noted

previously, Medicare will not pay for CDLTs on the CLFS unless they are furnished by laboratories that meet applicable CLIA certification requirements. Tests that examine materials derived from the human body are assigned to and paid under the CLFS only when furnished by such certified laboratories in accordance with 42 CFR 410.32(d). Because SaMS analyses performed on laboratory tests are downstream evaluations of the data generated by a prior laboratory test, an entity that performs only algorithmic analyses of previously sequenced data may not qualify as a CLFS laboratory under 42 CFR 493.2 or require CLIA certification. We believe SaMS that evaluate data generated by a prior laboratory test should not be treated as CDLTs for Medicare payment purposes.

We are also concerned that paying for these analyses based on existing CLFS payment methodologies may create significant vulnerabilities for the Medicare program, due to the lack of data transparency and CDLTs not being subject to beneficiary cost-sharing or budget neutrality. 42 CFR 414.508 outlines the ratesetting methodologies CMS uses to set payment rates for new tests on the CLFS. Under § 414.508(b), CMS determines the payment amount based on either crosswalking or gapfilling methodologies until applicable information is available to establish a payment amount under the methodology described in § 414.507(b). Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Gapfilling is used when no comparable existing CDLT is available. Public consultation for payment for a new clinical diagnostic laboratory tests is required in determining payment amounts, receiving public comments and recommendations (and data on which the recommendations are based) as well as recommendations from the Advisory Panel on CDLTs per 414.506. A significant challenge to the ratesetting process for CMS is the lack of transparent data received from laboratories outlining resource costs of a test, particularly for the algorithmic portions of tests that are combined with other analytes. In the past, laboratories have explained to CMS that the algorithmic components of laboratory tests are highly proprietary and details cannot be shared. Thus, CMS has worked with the limited information available on the details of methods or resources for the algorithmic portions of tests or analyses, and has thus far relied on other laboratory methods provided in the CPT descriptor (*i.e.* NGS sequencing, RT–PCR, or DNA methylation analysis). As CMS has gathered more information on SaMS analyses performed on laboratory tests, we now believe that since these analyses are entirely computer-based, comparison based on laboratory methodologies is not appropriate. Additionally, in contrast to the OPPS, the CLFS generally does not include beneficiary cost-sharing or budget neutrality adjustments, which limits transparency regarding pricing and creates challenges for ensuring appropriate valuation of these services.

Finally, CMS has an interest in ensuring that services that are fundamentally similar are paid for and treated in the same way, regardless of the setting of care in which the service is furnished. Since SaMS analyses performed on laboratory tests do not require performance by a CLIA-certified laboratory, and like many other SaMS analyses discussed in this section, perform algorithmic analyses on previously generated data, we believe SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the OPPS. Accordingly, we believe that whether the SaMS performs algorithmic analyses of an imaging test (*e.g.* CT scan) or whether it performs an algorithmic analysis on data generated from a laboratory test, all algorithmic analyses should be treated consistently. We believe that this uniform approach for SaMS technologies would promote stability and predictability in payment for similar services.

Therefore, for CY 2027, we propose to assign 10 HCPCS codes describing various SaMS analysis performed on laboratory tests to new technology APCs under the OPPS, using the latest available CLFS data to crosswalk to new technology APCs with payment rates that closely approximate the current CY 2026 CLFS payment rates for these codes. The proposed payment rates for SaMS performed on prior laboratory tests cannot be expected to align exactly with current CLFS payment rates because assignment to new technology APCs is based on established cost bands rather than individual test-specific payment amounts. For example, if a HCPCS code is currently paid $430.17 under the CLFS, the appropriate new technology APC assignment under this proposal would be APC 1506 (New Technology—Level 6 ($401–$500)), which has a standardized payment rate of $450.50, rather than receiving a payment rate that exactly matches the current CLFS amount. We note that, under this proposal, SaMS analyses performed on laboratory tests would be paid separately by being assigned to new technology APCs with the newly proposed status indicator ''O1'' (Software as a Medical Service, Paid under OPPS; separate APC payment) for CY 2027. Table 62 shows the list of currently payable SaMS analyses performed on laboratory tests under the CLFS with proposed new technology APC assignments under the OPPS for CY 2027. These 10 HCPCS codes were identified based on the CPT descriptor for the code. If there were no laboratory methods included in the code descriptor, and only an algorithmic analysis was described, we identified the code as a SaMS laboratory analysis. We would appreciate public comment on this proposed list and any other similar analyses that should be removed from the CLFS and paid under the OPPS.

In addition, for CY 2027 and subsequent years, we propose to assign any new SaMS analyses performed on laboratory test codes to new technology APCs for payment under the OPPS. We request public comment on these proposals, including the list of 10 HCPCS codes that we identified as SaMS analyses performed on laboratory tests and any additional HCPCS codes that we should designate as SaMS and pay under the OPPS rather than the CLFS. CMS may finalize a policy that includes such payment for additional HCPCS codes in the final rule based on public comment.

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TABLE 62: PROPOSED NEW TECHNOLOGY APC AND SI ASSIGNMENTS FOR SAMS ANALYSES PERFORMED ON LABORATORY TESTSFOR CY 2027

HCPCS Code	Long Descriptor	CY 2027 Proposed New Technology APC, SI
0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype	APC 1506 (New Technology - Level 6 ($401 - $500)), O1
0511U	Oncology (solid tumor), tumor cell culture in 3d microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug	APC 1524 (New Technology - Level 24 ($3001-$3500)), O1
0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0208U	Oncology (medullary thyroid carcinoma), mrna, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma	APC 1506 (New Technology - Level 6 ($401 - $500)), O1
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1-3, ret, ros1), and kras g12c and pd-l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate	APC 1509 (New Technology - Level 9 ($701 - $800)), O1
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (list separately in addition to code for primary procedure)	APC 1575 (New Technology - Level 38 ($10,001-$15,000)), O1

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C. Adjustment for Cost-of-Living in Alaska and Hawaii

We have heard from a variety of interested parties about the particularly difficult cost environment facing hospitals located in Alaska and Hawaii. These challenges stem from the unique circumstances of those geographies, including dependency on outside goods and components, remote locations and transportation challenges, and other factors inherent to providing healthcare in these non-contiguous States.

A review of the available cost report data used in OPPS ratesetting highlights these issues. We observe a number of hospitals in Alaska and Hawaii with payment-to-cost ratios (PCRs) that range from 0.6 to 0.7, significantly below the average PCR for OPPS hospitals of 0.89 used as an initial target for the cancer

hospital adjustment discussed in section II.F. of this proposed rule. In addition, the overall ancillary cost-to-charge ratios for several hospitals located in these States are higher than average, indicating that there are higher costs relative to what those hospitals are able to charge for the outpatient services they provide compared to other OPPS hospitals.

Under the IPPS, 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. To account for higher non-labor-related costs for these two States in the IPPS, we apply an adjustment factor to the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii. 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 U.S. 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 the existing IPPS 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).

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, effective for FY 2027, we propose to adjust non-labor related costs for hospitals located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data published by the Department of Defense (DOD). Starting with the FY 2027 payment year, we also propose to no longer cap the IPPS COLA factors at 25 percent. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule for further discussion of the proposed changes to the methodology for calculating the IPPS COLA factors for FY 2027 (91 FR 19813 through 19814).

While higher labor-related costs for these two States are taken into account under the OPPS through the adoption of the IPPS hospital wage index and associated wage index policies, the nonlabor portion of OPPS payment is not currently adjusted to address higher nonlabor costs in these States as is addressed in the IPPS through the COLA policy. We have historically adopted the IPPS wage index and wage index policies under the OPPS, most recently in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53494 through 53498). As discussed in section II.C of this proposed rule, we propose to continue to adopt the IPPS wage index and wage index policies under the CY 2027 OPPS and also continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. We think this same logic would apply to adopting the IPPS COLA policy for hospital outpatient services in Alaska and Hawaii, as additional nonlabor costs that apply to hospital inpatient services provided in these States likely also apply to hospital outpatient services in these States. Further, not addressing the discrepancy between the IPPS and OPPS adjustment to account for nonlabor related costs would potentially continue a disincentive to provide services in the hospital outpatient setting due to the adjustment only applying to inpatient services.

Based on our review of the costs of providing outpatient services in these States and our general practice of applying consistent policies across the inpatient and outpatient hospital settings where possible, we propose to use the equitable adjustment authority provided by section 1833(t)(2)(E) of the Act to propose to apply the IPPS COLA factors to the nonlabor share of OPPS payment amounts for hospitals located in Alaska and Hawaii for CY 2027 and future years. We note that for OPPS payments for which there is no wage adjustable portion, we propose to apply the COLA to the full OPPS payment, as would be the case for status indicator assignments of ''G,'' ''H,'' ''K,'' ''R,'' and ''U''.

As noted earlier in this section, in the FY 2027 IPPS/LTCH PPS proposed rule we proposed several changes to the current COLA methodology including using the OCOLA data published by the DOD for the FY 2027 factors as well as to remove the cap of 25 percent (91 FR 19813 through 19814). Consistent with our historical practice of aligning OPPS payment methodologies with those of the IPPS where appropriate, we propose to adopt the IPPS COLA factors as finalized in the FY 2027 IPPS/LTCH PPS final rule as the CY 2027 OPPS COLA factors for hospitals located in Alaska and Hawaii.

Under the OPPS, section 1833(t)(2)(E) of the Act grants the Secretary the authority to establish equitable adjustments as necessary, and we propose to use that authority to establish a COLA for outpatient hospital services provided in Alaska and Hawaii that mirrors the COLA provided for inpatient hospital services provided in these States. Associated with this proposed policy, we also propose to add conforming regulation text changes by adding subsection (l) to § 419.43. This new subsection describes the cost-of-living adjustment to the nonlabor portion of the OPPS payment amounts for hospitals located in Alaska and Hawaii. Finally, we note that under our authority at section 1833(t)(2)(E) of the Act this adjustment would be budget neutral, and the associated budget neutrality adjustment is discussed in section II.B. of this proposed rule.

D. Provision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR) and Pulmonary Rehabilitation (PR) Services to Hospital Outpatients in Their Homes Via Audio and Video Real-Time Communications Technology

Section 6211(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026), amended section 1861(eee)(2)(A)(ii) of the Act to allow for the provision of cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR) and pulmonary rehabilitation (PR) services to hospital outpatients in their homes via audio and video real-time communications technology (excluding audio-only), through December 31, 2027.

Section 6211(b) of CAA, 2026, authorizes the Secretary to implement the amendment made by section 6211(a) via program instruction or otherwise. Consistent with that authority, we have issued sub-regulatory guidance relating to the provision of CR, ICR and PR services to hospital outpatients in their homes via audio and video real-time communications technology. This guidance is available at *https://www.cms.gov/medicare/coverage/telehealth.*

XI. Proposed CY 2027 OPPS Payment Status and Comment Indicators

A. Proposed CY 2027 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code.

For CY 2027 and subsequent years, we propose to create a new status indicator for software as a medical service that is paid separately under the OPPS. Under the OPPS, software as a medical service that is paid separately would be assigned a status indicator of ''O1''—(Software as a Medical Service, paid under OPPS; separate APC payment). Further discussion of the proposed payment policy for SaMS can be found in section X.B of the CY 2027 OPPS/ASC proposed rule. The proposed definition and payment status of proposed status indicator ''O1'' can be found in Table 63.

TABLE 63: PROPOSED DEFINITIONS AND PAYMENT STATUSES OF PROPOSED STATUS INDICATORS O1 AND E2

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
O1	Software as a Medical Service, paid under OPPS; separate APC payment.	Paid under OPPS; separate APC payment.
E2	Items and Services: For which pricing information and claims data are not available.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Exception: claims under drug invoice pricing policy are contractor priced.

For CY 2027 and subsequent years, we also propose to revise the current definition of status indicator ''E2'' to comply with the drug invoice policy. Further discussion of the proposed drug invoice payment policy can be found in section V.2.c of this proposed rule. The proposed revised definition of status indicator ''E2'' can be found in Table 63.

We do not propose to make any other changes to the existing definitions of status indicators that are listed in Addendum D1 to this proposed rule which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

The complete list of proposed CY 2027 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.* The proposed CY 2027 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

We solicit public comments on the proposed definitions of the OPPS payment status indicators for CY 2027.

B. Proposed CY 2027 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2027 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2026; and we propose to continue their use in CY 2027. The proposed CY 2027 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the CY 2026 OPPS/ASC proposed rule; final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments

will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2027 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

We solicit public comments on our proposed definitions of the OPPS comment indicators for CY 2027.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make interested parties aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2026 report.

A. OPPS Payment Rates Update

The March 2026 MedPAC ''Report to the Congress: Medicare Payment Policy'', recommended that the Congress update Medicare OPPS payment rates by the amount specified in current law. We refer readers to the March 2026 report for a complete discussion of this recommendation.[152] We appreciate MedPAC's recommendation and, as discussed further in section II.B. of this proposed rule, we propose to increase the OPPS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

In the March 2026 MedPAC ''Report to the Congress: Medicare Payment Policy'', MedPAC stated that their recommended update to IPPS and OPPS payment rates under current law may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommended we redistribute 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 recommended adding $1 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to the Congress transitional approaches for an MSNI policy. The FY 2027 IPPS/LTCH proposed rule (91 FR 19312) provides additional information regarding statutory requirements for disproportionate share hospital and uncompensated care payments. We look forward to working with the Congress on these matters.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2026 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; 87 FR 72054 through 72096; 88 FR 81900 through 81961; 89 FR 94309 through 94367; and 90 FR 53834 through 53916).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle, is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes

[152] Medicare Payment Advisory Committee. March 2026 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.61–96. Available at *https://www.medpac.gov.*

Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in the proposed rule (and respond to those comments in the CY 2027 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2027 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2028 OPPS/ASC final rule with comment period).

2. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2026 ASC quarterly update (Transmittal 13704, dated April 7, 2026, CR 14445), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 64 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2026) of this proposed rule, lists the new Level II HCPCS codes that were implemented April 1, 2026. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2026, are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that the following ASC addenda and OPPS Addendum O are available via the internet on the CMS website.

- ASC Addendum AA: Proposed ASC Covered Surgical Procedures for CY 2027 (Including Surgical Procedures for Which Payment is Packaged),
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2027 (Including Ancillary Services for Which Payment is Packaged),
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2027,
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2027,
- ASC Addendum EE: Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2027, and
- ASC Addendum FF: Proposed ASC Device Offset Percentages for CY 2027, and
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2027.

We invite public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2026 through the quarterly update CRs, as listed in Table 64 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2026) of this proposed rule. We propose to finalize their payment indicators in the CY 2027 OPPS/ASC final rule with comment period.

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TABLE 64: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE APRIL 1, 2026

HCPCS Code	Long Descriptor
A2040	Microlyte painguard, per square centimeter
A2041	Foundation drs+ duo, per square centimeter
A2042	Foundation drs+ solo, per square centimeter
A2043	Biobrane, per square centimeter
A2044	Biobrane glove, each
A2045	Novashield or novogen wound matrix, per square centimeter
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring an insertion of a separate distal respiratory sensor electrode or electrode array
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8010	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C9818	suzetrigine, oral, 1 mg
G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
G0682	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
G0683	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
G0684	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area or part

HCPCS Code	Long Descriptor
	thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
J0463	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg
J1098	Articaine ophthalmic, 8% solution, 0.4 mL
J1164	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	Injection, immune globulin (yimmugo), 100 mg
J8502	Injection, aprepitant (aponvie), 1 mg
J9183	Gemcitabine intravesical system, 225 mg
J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
J9278	Injection, carboplatin (avyxa), 1 mg
J9601	Injection, linvoseltamab-gcpt, 1 mg
Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4419	Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4421	Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)
Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4425	Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)
Q4426	Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4427	Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4429	Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4435	Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Pretect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4439	Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg

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3. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2026 ASC quarterly update (Transmittal R13836, Change Request 14522, June 24, 2026), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 65 (New HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective July 1, 2026) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2026. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2026, are assigned to comment indicator ''NP'' in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their

interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

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TABLE 65: NEW HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2026

HCPCS Code	Long Descriptor
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
A9574	Injection, ferumoxytol, 1 mg
C1609	Vertebral device, motion-preserving, with screw fixation
C8014	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)
C9310	Injection, leucovorin calcium (avyxa), 1 mg
J0528	Injection, fosfomycin disodium, 20 mg
J1289	Injection, narsoplimab-wuug, 1 mg
J1577	Injection, immune globulin (qivigy), 100 mg
J2361	Injection, depemokimab-ulaa, 1 mg
J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL
J7176	Injection, human fibrinogen - chmt (fesilty), 1 mg
J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj
J9232	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg
Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg
Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg
Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg
Q5168	Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
Q5169	Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg
Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg
Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg

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We invite public comments on the proposed payment indicators for the new HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services effective April 1, 2026 and July 1, 2026, through the quarterly update CRs, as listed in Tables 64 and 65. We propose to finalize the payment indicators in the CY 2027 OPPS/ASC final rule with comment period.

4. October 2026 HCPCS Codes Final Rule Comment Solicitation

For CY 2027, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2026, would be ''NI'' in Addendum BB to the CY 2027 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2026. We will invite public comments in the CY 2027 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

5. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2027 OPPS/ASC

final rule with comment period, January 2027 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2027, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the CY 2027 OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2027, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2027 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2027 ASC update, we received the CPT codes that will be effective January 1, 2027, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the code is new for the next calendar year, or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2027 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appeared in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new CY 2027 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled ''CY 2027 OPPS/ASC Proposed Rule 5-Digit Placeholder Code''. We intend to include the final CPT code numbers in the CY 2027 OPPS/ASC final rule with comment period.

In summary, we solicit public comments on the proposed CY 2027 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2027. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2027 OPPS/ASC final rule with comment period. The proposed payment indicators and comment indicators for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new CPT codes that will be effective January 1, 2027, are assigned to comment indicator ''NP'' in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim payment ASC payment assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 66, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

TABLE 66: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED ASC-RELATED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2026	HCPCS (CPT and Level II codes)	April 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II codes)	July 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II codes)	October 1, 2026	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period
January 2027	CPT Codes	January 1, 2027	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period

6. Proposed ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, NTIOLs, or qualifying nonopioid devices. We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497). The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment. In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available. In CY 2024 OPPS/ASC final rule with comment period, we finalized the addition of two ASC payment indicators, ''D1''—''Ancillary dental service/item; no separate payment made'' and ''D2''—''Non office-based dental procedure added in CY 2024 or later'', for new dental codes for CY 2024 and subsequent calendar years to indicate potentially payable dental services and procedures in the ASC setting (88 FR 81907). We added these two codes to Addendum DD1 (which is available via the internet on the CMS website). In CY 2025 OPPS/ASC final rule with comment period, we finalized the modification of the descriptor of ASC payment indicator ''L6'' to ''Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices'', to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023 (89 FR 94317).

We added this code to Addendum DD1 (which is available via the internet on the CMS website). In CY 2026 OPPS/ASC final rule with comment period, we finalized the addition of one payment indicator, ''S2''—''Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate'' to describe skin substitute products paid separately in an ASC (90 FR 53843). We added this code to Addendum DD1 (which is available via the internet on the CMS website).

b. Proposed ASC Payment and Comment Indicators for CY 2027

For CY 2027, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2027 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2027, compared to the CY 2026 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2027 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2027 update. Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2027.

C. Proposed Payment Policies Under the ASC Payment System

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b. of this proposed rule, we update the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3'', and ''R2'') using the most recent available PFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which is lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4. of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2027

We propose to update ASC payment rates for CY 2027 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4. of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We propose to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4. of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2027 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2027 PFS nonfacility PE RVU-based amount or the proposed CY 2027 ASC payment amount calculated

according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2026, for CY 2027, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed Payment for ASC Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain ''J1'' service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b. of this proposed rule, we apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and add-on codes from the originating Comprehensive APC (C–APC) (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. A ''J1'' status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b. of this proposed rule, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator ''J1'' or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of ''J1'' services, or combinations of a ''J1'' service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described previously, we promote the claim to the next higher cost C–APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new C–APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the proposed complexity adjustments for ''J1'' and add-on code combinations for CY 2027, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

(2) CY 2027 ASC Special Payment Policy Proposal for OPPS Complexity-Adjusted C–APCs

For CY 2027, we propose to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080). We also propose to make a minor change to the long descriptor of ASC complexity adjustment code C7570.

For those ASC complexity adjustment codes for which we have claims data, we propose to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations for CY 2027. Any ASC complexity adjustment budget neutrality calculations are discussed further in section XIII.H.2.a. of this proposed rule. The full list of the proposed ASC complexity adjustment codes, inactive ASC complexity adjustment codes, their short descriptors, long descriptors, and proposed ASC payment indicators for CY 2027 can be found in the CY 2027 proposed ASC CPX supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions. ASC Addendum AA also includes our proposed active ASC complexity adjustment codes and their ASC payment rates. Both files are published on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notices.* Since the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for the proposed payment policy changed slightly from the previous year. Additionally, since complexity adjustment assignments may change between the proposed rule and final rule under the OPPS, the final list of ASC complexity adjustment codes eligible for this payment policy may be slightly different than the proposed list of ASC complexity adjustment codes.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100

claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for the CY 2027 OPPS/ASC proposed rule, we propose to designate five brachytherapy APCs and four clinical APCs as Low Volume APCs under the ASC payment system. The four clinical APCs and five brachytherapy APCs met our criteria of having fewer than 100 single claims in the relevant claims year (CY 2025 for the CY 2027 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Eight of the nine APCs were designated as Low Volume APCs in CY 2026. Based on data for the CY 2027 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) had 87 single claims and now meets our criteria to be designated as a Low Volume APC.

Table 67 includes the CY 2025 claims available for ratesetting for each of the APCs we propose to be designated as a Low Volume APCs for CY 2027. The cost statistics for our Low Volume APCs, such as the median, arithmetic mean, and geometric mean costs, are available for download with this proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/ascregulations-and-notices;* click on the relevant regulation to download the Low Volume APC cost statistics under the standard (ASC) ratesetting methodology in the ''Downloads'' section of the web page.

TABLE 67: PROPOSED LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2027

APC	APC Description	CY 2025 Claims Available for Ratesetting
2635	Brachytx, non-str, HA, P-103	28
2642	Brachytx, stranded, C-131	41
2643	Brachytx, non-stranded,c-131	78
2645	Brachytx, non-str, gold-198	87
2647	Brachytx, NS, Non-HDRIr-192	13
5244	Level 4 Blood Product Exchanges and Related Services	2
5494	Level 4 Intraocular Procedures	11
5495	Level 5 Intraocular Procedures	34
5496	Level 6 Intraocular Procedures	12

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indicator ''N1'') under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear

medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the PFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoice costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3'', and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53887 through 53888), we finalized our policy to unpackage and pay separately for certain skin substitute supplies when provided integral to a covered surgical procedure under the ASC payment system in conjunction with our policy to unpackage and pay separately for the same such items under the OPPS. We finalized the addition of a new ASC payment indicator ''S2''—''Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate'' to indicate a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure. We finalized that payment for separately payable skin substitute supplies under the ASC payment system would be made at the same rate as is provided under the OPPS.

b. Proposed Payment for Covered Ancillary Items and Services for CY 2027

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2027 OPPS and ASC payment rates and subsequent years' payment rates. We propose to continue to set the proposed CY 2027 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs, biologicals, and skin substitute supplies equal to the OPPS payment rates for CY 2027 and subsequent years' payment rates.

Covered ancillary services and their proposed payment indicators for CY 2027 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2027. For a discussion of the PFS rates, we refer readers to the CY 2027 PFS proposed rule with comment period which is available on the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-n*otices.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recently available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that final rule, we also finalized our policy to exempt all

procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that final rule with payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with PFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with PFS nonfacility PE RVUs; payment based on PFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without PFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the PFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2027 Proposed Office-Based Procedures

In developing the CY 2027 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. Historically, we also review the most recent claims volume and utilization data (CY 2025 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2026 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2,'' ''P3'', or ''R2'' in the CY 2026 OPPS/ASC final rule with comment period (89 FR 94322 through 94326).

Our review of the CY 2025 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of two surgical procedures—CPT code 0102T (Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle) and 60660 (Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency)—that we believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. We have included CPT codes 0102T and 60660 in our list of surgical procedures we propose to permanently designate as office-based for CY 2027 in Table 68.

TABLE 68: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICEBASED FOR CY 2027

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Proposed CY 2027 ASC Payment Indicator*
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle	G2	P2*
60660	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency	G2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS proposed rates.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence of claims data, we use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

In Table 130 of the CY 2026 OPPS/ASC final rule with comment period, we finalized assigning temporary office-based designations to four surgical procedures for CY 2026 (90 FR 53850). We reviewed CY 2025 volume and utilization data for the four surgical procedures designated as temporarily office-based in the CY 2026 OPPS/ASC final rule with comment period. As shown in Table 69 of this proposed rule, for one of the four surgical procedures—CPT code 53866 (Catheterization with

removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate)—there are greater than 50 claims available and the volume and utilization indicated this procedure was not performed predominantly in the office setting based on CY 2025 claims data. Therefore, we propose to no longer designate this procedure as temporarily office-based and to designate this procedure a payment indicator of ''G2''—'' 'Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.'' for CY 2027.

TABLE 69: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2027

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Proposed CY 2027 ASC Payment Indicator*
53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	R2	G2

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS proposed rates.

For the remaining three procedures that were designated as temporarily office-based in the CY 2026 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2'', ''P3'', or ''R2,'' there were fewer than 50 claims; therefore, there was an insufficient number of claims to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 70, we propose to continue to designate such procedures as temporarily office-based for CY 2027 and assign one of the office-based payment indicators. Additionally, for CY 2027, we did not propose to designate any new CY 2027 CPT codes for ASC covered surgical procedures as temporarily office-based.

The procedures for which the proposed office-based designation for CY 2027 is temporary are also indicated by an asterisk in Addendum AA to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ASCPayment/ASCRegulations-and-Notices*).

TABLE 70: CY 2027 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE DESIGNATED AS TEMPORARILY OFFICE-BASED

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Proposed CY 2027 ASC Payment Indicator*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS proposed rates.

4. Proposed Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = ''N1'') procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPPS complexity adjustment code's APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the ''device offset amount'') and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, we apply our standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a modification to our policy regarding default device offset percentages for new codes that meet our criteria for device-intensive status. Under both the OPPS and ASC payment system, for new device-intensive procedures that lack claims data, or lack claims data from a predecessor code or a clinically-similar code that uses the same device, we apply the greater of the APC-wide device offset percentage or 31 percent (the previous default device offset percentage). We believe that an APC-wide average device offset percentage is, in most cases, a better reflection of device costs when the typical device costs of procedures assigned to such APC are significantly greater than 31 percent. This policy does not apply to new device-intensive procedures assigned to New Technology APCs.

In the CY 2026 OPPS/ASC final rule with comment period, we discussed the implementation of the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 rule and the impact of the OPPS conversion factor on the ASC payment system. Since most ASC payment rates for surgical procedures are constructed from OPPS relative weights or the PFS unadjusted nonfacility PE RVU-based amount, the remedy's proposed prospective offset to the OPPS conversion has a very limited impact on the ASC payment system. The only impact of the proposed reduction to the OPPS conversion factor is the payment rate for device-intensive procedures under the ASC payment system. Since the ASC payment system holds device portions constant between the two settings, the device portion is the device offset percentage multiplied by the OPPS payment rate. As we stated in that rule, we believed it would be inaccurate and inappropriate to use OPPS payment rates that have been reduced by the remedy's prospective offset since this could accumulate to have a potentially noticeable impact on ASC payment rates for certain device-intensive procedures over time. Therefore, we finalized our policy that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not incorporate the prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that we proposed to implement in the CY 2026 OPPS/ASC proposed rule.

As discussed in section XIII.G.2.a. of this proposed rule, historically, the device portions of device-intensive procedures have not been scaled so that payment for device portions would remain constant between the OPPS and ASC payment system. However, due to increased utilization of orthopedic procedures in the ASC setting, ASC expenditures on device portions of device-intensive procedures represent a substantially larger share of total ASC expenditures than in prior years. For this proposed rule, we estimate a proposed large increase in the device portions for device-intensive procedures as a result of the proposed 340B drug payment policy which results in a large decrease in the ASC weight scaler. We solicit comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scaler. If we were to include device portions as subject to scaling, ASC payment rates for device-intensive procedures would decrease and ASC payment rates for non-device intensive procedures would increase. We estimate that treating device expenditures for device-intensive procedures as scalable prospective expenditures would increase the proposed ASC weight scaler from 0.809 to 0.865 in CY 2027 but would decrease the ASC payment for the device portion of device intensive procedures by approximately 14 percent.

We are not proposing any changes to our device-intensive procedure policies under the ASC payment system for CY 2027, but we are soliciting comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler or whether device portions should represent scalable prospective expenditures. For the proposed CY 2027 device offset percentages, which include device offset percentages based on CY 2025 claims processed through March 31, 2026, we refer readers to Addendum FF of the CY 2027 OPPS/ASC proposed rule. Final CY 2027 device offset percentages may differ from the proposed percentages as we rely on the most recently available claims data for the CY 2027 OPPS/ASC final rule with comment period (CY 2025 claims data processed through June 30, 2026).

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We are not proposing any changes to our policies related to no cost/full credit or partial credit devices for CY 2027.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Proposed Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the

list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by interested parties.

Under our current regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2026, are surgical procedures that meet the criteria specified in § 416.166(b)(2). In the CY 2026 OPPS/ASC final rule with comment period, we finalized a policy to expand the ASC CPL by revising our criteria for adding surgical procedures to the ASC CPL (90 FR 53855 through 53886). Under the revised criteria, procedures added to the ASC CPL must be separately paid under the OPPS and are not (1) currently designated as requiring inpatient care under § 419.22(n), (2) only able to be reported using a CPT unlisted surgical procedure code, or (3) otherwise excluded under § 411.15. Additionally, we moved certain general standards and exclusions used to evaluate services for addition to the ASC CPL prior to January 1, 2026, to a new section of the following non-binding physician considerations: (1) Is not expected to pose a significant safety risk when performed in an ASC; (2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure; (3) Generally results in extensive blood loss; (4) Requires major or prolonged invasion of body cavities; (5) Directly involves major blood vessels; (6) Is generally emergent or life- threatening in nature; and (7) commonly requires systemic thrombolytic therapy. We believe that these revised criteria are sufficient to ensure, along with appropriate patient selection and complex medical judgement of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve the five previous exclusion criteria. We believe that this expansion of the ASC CPL could advance the goals of increasing physician and patient choice and expanding site neutral options in conjunction with patient safety considerations. For further discussion on our policy to revise the ASC CPL criteria and expand the procedures added to the list, please refer to section XIII.D. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53855 through 53886).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the criteria established in previous years for addition to the ASC CPL.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 through CY 2026 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; 88 FR 81923 through 81945; 89 FR 94331 through 94334; and (90 FR 53855 through 53886).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2027

Historically, we have reviewed the clinical characteristics of procedures and consulted with appropriate medical organizations, other interested parties, and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 42 CFR 416.166.

As part of our evaluation process to add procedures to the CPL, we assess potential procedures against the revised ASC CPL criteria at § 416.166(b)(2). For CY 2027, we reviewed interested parties' nominations received in the pre-proposed rule nominations process. Additionally, we reviewed procedures that are proposed to be removed from the IPO list for CY 2027, as part of the continuation of the elimination of the IPO list, as described in section IX. discussed earlier in this proposed rule. Based upon this review, we propose to update the ASC CPL by adding 618 procedures that we propose to remove from the IPO list for CY 2027. This includes four procedures that were recommended by interested parties for addition to the ASC CPL: CPT code 49596 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated), 49616 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated), 40617 (Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), and 40618 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated). We believe these procedures would meet the revised ASC CPL criteria under 42 CFR 416.166, if we finalize our proposal to remove these services from the IPO list for CY 2027. These procedures are listed in the public use file titled ''Proposed Additions to the List of ASC Covered Procedures for CY 2027,'' which is available on the CMS website.

3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174; and (7) groups of skin substitute supply products. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy

to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2026, but will be packaged under the CY 2027 OPPS, we would also package the ancillary service under the ASC payment system for CY 2027 to maintain consistency with the OPPS. Comment indicator ''CH'' is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2025.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise § 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490). In the CY 2025 OPPS/ASC final rule with comment period, we revised § 416.164(b)(6) to read ''Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174,'' as we finalized a policy to place qualifying medical devices on the ASC covered ancillary services list (89 FR 94361).

In the CY 2026 OPPS/ASC final rule with comment period, we finalized our proposal to pay separately for the provision of certain groups of skin substitute products when used during a covered surgical procedure, by revising § 416.164(b) to include groups of skin substitute products as covered ancillary items and services that are integral to a covered surgical procedure.

E. Proposed CY 2027 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, paragraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Paragraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act.

Additional payments under this policy began on January 1, 2025. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94344), the statute directs CMS to provide ''additional payment'', and for purposes of this policy, we interpret this language to be equivalent to ''separate payment,'' since CMS provides an additional payment by unpackaging the product and then making a separate payment. ''Separate payment'' is the more commonly used terminology in the OPPS rule and likely more familiar to readers. To avoid confusion, we will continue to use ''separate payment'' throughout the rest of this section, which we believe to be synonymous with ''additional payment.'' Under section 1833(t)(2)(E) of the Act, the temporary separate payments must be made in a budget neutral manner.

For background information on the ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs and Biologicals prior to CY 2025, please see the summary provided in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94343).

2. Finalized CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2025, CMS finalized our implementation methodology for section 4135 of CAA, 2023 (89 FR 94343 through 94361) to provide for temporary separate payments for certain non-opioid treatment for pain relief in the hospital outpatient department and ambulatory surgical center settings on a temporary basis from January 1, 2025 through December 31, 2027. CMS also finalized regulation text at 42 CFR 416.174 and 42 CFR 419.43(k), which outline the payment for non-opioid pain management drugs, biologicals, and medical devices under both the ASC payment system and OPPS, respectively.

a. Drugs and Biologicals Subject to the ASC Non-Opioid Policy (42 CFR 416.174)

Section 1833(i)(10)(B), titled ''Transition'', provides that a drug or biological that meets the requirements of the regulation at 42 CFR 416.174, the current ASC non-opioid policy, and also meets the definition of a non-opioid treatment for pain relief at section 1833(t)(16)(G)(iv) of the Act shall receive separate payments under section 4135 of the CAA, 2023, subject to the payment limitation. In light of this requirement, we finalized in the CY 2025 OPPS/ASC final rule with comment period that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 of the CAA, 2023 that were subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act in CY 2024, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135 of the CAA, 2023 (89 FR 94344).

b. Definition of Non-Opioid Treatment for Pain Relief

Section 1833(t)(16)(G)(iv) of the Act defines a non-opioid treatment for pain relief for a drug, biological product, or medical device and requires, in part, that such treatment does not receive transitional pass-through payment and

has payment that is packaged into a payment for a covered OPD service (or group of services). In addition, in order for a drug or biological product to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(I), the product must have ''a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors''. In order for a medical device to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(II) of the Act, it must, in part, be ''used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia''. A medical device must also, pursuant to section 1833(t)(16)(G)(iv)(II)(aa) and (bb) of the Act have both ''an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act'' and ''demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal''.

c. Evidence Requirement for Medical Devices

To determine whether a medical device fulfills the statutory requirement that it has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, we finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345) a policy to review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids. In CY 2025, we encouraged interested parties submitting non-opioid device recommendations to submit any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision with their public comments. We review any literature submitted and determine whether it meets this evidence criterion. There is no requirement that commenters submit any data or literature with their device recommendations. If there is no data or literature submitted for a medical device, or if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, the medical device would not meet this evidence criterion and would not qualify for separate payment under section 4135 of the CAA, 2023.

d. Non-Opioid Product Indications

(1) FDA-Approved Indications for Drugs and Biologicals

Section 1833(t)(16)(G)(iv)(I) of the Act specifies that to meet the definition of a non-opioid treatment for pain relief and to be eligible for separate payment, a drug or biological product must have a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

Given these statutory requirements, we finalized a policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346) only to approve separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia. We noted that products without an indication that meets this statutory requirement would not qualify. We specifically stated that products with only a general pain indication will not qualify.

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346), we note that the Congress specifically included language at section 1833(t)(16)(G)(iv)(I) of the Act requiring that drugs or biologicals have ''a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors''. Therefore, products without an indication that meets the statutory requirement will not qualify.

(2) Intended Use for Medical Devices

Regarding medical devices, section 1833(t)(16)(G)(iv)(II) of the Act specifies that such a device must be used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia to qualify for separate payment under section 4135 of the CAA, 2023. It also must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), have been cleared for market under section 510(k) of the FD&C Act, or be exempt from the requirements of section 510(k) of the FD&C Act pursuant to section 510(l) or (m) or 520(g) of the FD&C Act. For CY 2025, for medical devices, we finalized without modification our proposal that a device must be used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia to qualify for separate payment under section 4135 of the CAA, 2023 (89 FR 94346 through 94347). We also finalized that the medical device must have an application approved under section 515 of the FD&C Act, which has been cleared for market under section 510(k) of the FD&C Act, or be exempt from the requirements of section 510(k) of the FD&C Act pursuant to sections 510(l) or (m) or 520(g) of the FD&C Act. (89 FR 94346 through 94347). This is consistent with the regulation text at 42 CFR 419.43(k)(2)(i) through (iv).

e. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act provides that, for a non-opioid treatment for pain relief that is a drug or biological product, the amount of separate payment is the amount of payment for such product determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to a limitation, as described in the next section. Section 1833(t)(16)(G)(ii)(II) of the Act provides that, for a non-opioid treatment for pain relief that is a medical device, the amount of separate payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to a limitation, as described in the next section.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025 (89 FR 94347 through 94348). A zero dollar offset means that we would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates. We finalized a zero dollar offset for the initial year of the policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected yet in the cost of procedures in which they may be used. Therefore, we stated that the separate payment for a drug or biological would be determined

by subtracting from the amount calculated using the methodology outlined in section 1847A of the Act the portion of the otherwise applicable Medicare OPD fee schedule associated with the drug or biological, which as previously discussed, we finalized to be zero dollars for CY 2025. For the amount of payment for a medical device, since we are unable to reduce charges to costs for ASCs, we stated that the separate payment amount would be contractor-priced by the ASC's Medicare Administrative Contractor reduced by the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we finalized to be zero dollars for CY 2025. These separate payment amounts are all subject to the payment limitation, described in the subsequent section.

Section 1833(i)(10) of the Act establishes the same separate payment for the ASC setting as for hospital outpatient departments, as described in section 1833(t)(16)(G)(ii) of the Act. Both separate payments are subject to the limitation in section 1833(t)(16)(G)(iii) of the Act, which specifies that the separate payment amount shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished. Given this statutory requirement, we finalized paying the same separate payment amount for qualifying non-opioid products in both the HOPD and ASC settings starting on January 1, 2025 through December 31, 2027.

As the statute requires separate payment for these non-opioid treatments for pain relief, these products cannot be packaged into the procedure payment. Under our current threshold packaging policy, if the estimated per day cost for a drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure. Similarly, under our comprehensive APC (C–APC) policy, we package all payments for services integral, ancillary, supportive, dependent, and adjunctive to the primary service into a single payment for the primary comprehensive service. For CY 2025, we finalized that non-opioid treatments for pain relief would not be subject to the threshold packaging policy and would also be separately paid when used during a comprehensive APC (C–APC) procedure in the HOPD setting (89 FR 94347 through 94348). See section V.B.1.a. of this proposed rule for more information regarding the drug packaging threshold. Section II.A.2.b. of this proposed rule contains further information on C–APC packaging.

f. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the separate payment amount specified in clause (ii), (which is described in the previous section) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to base the 18 percent payment limitation on the volume weighted average of the payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy. We also finalized applying the 18 percent payment limitation per date of service billed (89 FR 94349).

g. Payment Limitation With No Claims Data

For drugs, biologicals, and devices with no claims data, such as for newly FDA-approved and marketed products or products that did not previously have their own product-specific HCPCS code by which to track payment and utilization data, we finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94350) a policy where CMS will utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, to calculate the payment limitation based on expected clinical use patterns. The finalized policy stated that CMS will determine the service, or group of services, to use to calculate the payment limitation through engagement with interested parties and a review by CMS Medical Officers and clinical staff during annual rulemaking. In the absence of engagement from interested parties, we will determine clinically appropriate procedures with which we would expect the drug or device to be frequently used in order to determine the payment limitation, including review of FDA approval materials, procedures identified in literature available to CMS, and other relevant materials. We noted that we may update the payment limitation amount in future rulemaking as we gather additional claims data on the utilization of and payment for this product.

3. Final CY 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2026, we finalized to continue the policies implemented in the CY 2025 OPPS ASC final rule (90 FR 53888 through 53909), with minor modifications to permit timely consideration of qualifying products. In that final rule we finalized to maintain a zero-dollar offset for all qualifying products regulated under the non-opioid policy, consistent with our belief that costs for some of these products may not be fully reflected yet in the cost of procedures in which they may be used. Additionally, the data used for CY 2026 ratesetting was derived from CY 2024 claims, which was prior to the effective date of this policy in CY 2025. We also finalized conforming regulatory text changes at 42 CFR 416.174(c)(1) to remove language specific to CY 2025, allowing us to consider or revise the offset amount through annual rulemaking.

We finalized a list of qualifying drugs, biologicals, and devices that meet the statutory criteria for separate payment under section 4135. Similarly, we finalized payment limitation calculations for the qualifying non-opioid products, and finalized our approach to determining those payment limitations based on the proposed procedure payment rates and utilization data available in the CY 2026 OPPS/ASC proposed rule, which we stated was the best data available at the time of writing the CY 2026 OPPS/ASC proposed rule.

In response to public comments, we finalized a modification to allow for more timely consideration of qualifying products by establishing a process to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis, rather than limiting consideration to annual rulemaking. We also made conforming regulatory text revisions at 42 CFR 419.43(k) and 416.174 to remove references tying qualification only to annual rulemaking.

4. Proposed CY 2027 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

For CY 2027, we propose to continue the policies finalized in the CY 2026 OPPS/ASC final rule without modification (90 FR 53448), aside from a technical modification to the payment limitation calculations as described further in this section.

We continue to believe a zero-dollar offset is appropriate for all qualifying products regulated under the non-opioid policy as some of these products

are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected in the cost of procedures in which they may be used. Additionally, given the clinical nature of non-opioid treatments for pain relief, they can be used in a variety of procedures, making an APC offset impractical. A continued zero-dollar offset aligns with comment support for a zero-dollar offset as discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53892).

We note that the payment limitation calculations will now be displayed in a public use file for the proposed rule. The non-opioid payment limitation public use file is available on the CMS website under downloads for the CY 2027 OPPS proposed rule. By including the payment limitations in the public use file, we are able to use the most recently available data to calculate the payment limitations. Therefore, the payment limitations calculated for this proposed rule will be based on the payment rates and utilization data available for this proposed rule. Accordingly, the final payment limitation calculation in the CY 2027 OPPS/ASC final rule with comment period will be based on the final rule procedure payment rates and utilization data available for the final rule. Therefore, there could be slight changes between the proposed rule payment calculations and the final rule payment calculations as the payment rates and utilization data is updated between the proposed and final rules.

Table 71 includes the drugs and biologicals we propose to have met the statutory requirements and qualify for separate payment for this CY 2027 OPPS/ASC proposed rule. Given our updated policy to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis finalized in the CY 2026 OPPS/ASC final rule with comment period, we anticipate that we will incorporate additional qualifying non-opioid products into Table 71 in the final rule with comment period. For parties interested in submitting additional products for consideration under this policy, we refer readers to the guidance posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/non-opioid-treatments-pain-relief.* We will review eligible products as provided in the guidance.

We welcome comments on our proposals.

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TABLE 71: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN CY 2027 UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor
Exparel	J0666*	Injection, bupivacaine liposome, 1mg
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Zynrelef	J0668 (previously C9088**)	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
Journavx	C9818	suzetrigine, oral, 1 mg
Caldolor	J1741	Injection, ibuprofen, 100 mg
ON-Q Pump	C9804	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
SPRINT Peripheral Nerve Stimulator System	C9807	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Cryo Nerve Block Therapy	C9808	Nerve cryoablation probe (e.g., cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump	C9806	Rotary peristaltic infusion pump (e.g., ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Iovera System	C9809	Cryoneurolysis needle (e.g., iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
IceMan	C9810	Water circulating motorized cold therapy device (e.g., IceMan) including all system components (e.g. pads, console, disposable parts), non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the cCAA 2023)
Sapphire Infusion Pump	C9811	Electronic ambulatory infusion pump (e.g. Sapphire pump), including all pump components, including disposable components , non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)

Brand Name	HCPCS Code	Long Descriptor
Ultrasound-visible nerve block needles (SonoPlex, SonoBlock, SonoTap)	C9812	Echogenic nerve block needles (e.g. SonoPlex, SonoBlock, SonoTap), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Perforated continuous infusion catheter set (InfiltraLong)	C9813	Perforated continuous infusion catheter set (e.g. InfiltraLong), including all components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Continuous anesthesia conduction catheter sets (SonoLong, E-Cath)	C9814	Continuous anesthesia echogenic conduction catheter set (e.g. SonoLong, E-Cath), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
CADD-Solis infusion pump	C9815	Linear peristaltic pain management infusion pump (e.g. CADD-Solis ambulatory infusion pump), and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump (Reusable)	C9816	Rotary peristaltic infusion pump (e.g., reusable ambIT Pump) including all disposable system components, reusable non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Game Ready System	C9817	Electronic cryo-pneumatic compression, pain management system (e.g. Game Ready® GRPro 2.1 System), including control unit, anatomically correct wrap(s), and other system component(s), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)

*Previously described by HCPCS code C9290.

**HCPCS Code C9088 was replaced by HCPCS code J0668 (Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg) effective October 1, 2025.

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F. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

• Applicants submit their NTIOL requests for review to CMS by the annual deadline which is announced in the annual OPPS/ASC final rule with comment period. For a request to be considered complete, we require submission of the information requested in the guidance document titled ''Application Process and Information Requirements for Requests for a New Class of NTIOLs or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols.*

• We announce annually, in the CY OPPS/ASC proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests to establish a new NTIOL class as published in the proposed rule.

• In the final rule with comment period updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2027

We did not receive any requests for review to establish a new NTIOL class for CY 2027 by March 1, 2026, the due date published in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53910).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2027.

G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule with comment period (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2. of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the PFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive-procedures).

As discussed in the August 2, 2007 ASC final rule with comment period (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to acute care hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes result in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the pre-floor, pre-reclassified hospital wage indexes, which are updated yearly and are used by several other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs (89 FR 23424). Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index for the fiscal year under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On July 21, 2023, OMB issued OMB Bulletin No. 23–01, which provided the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the U.S. and Puerto Rico based on the standards published on July 16, 2021, in the **Federal Register** (86 FR 37770) and 2020 Census Bureau data. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.) As discussed in the FY 2025 IPPS/LTCH PPS final rule with comment period (89 FR 69253 through 69266), we finalized our proposal to use the new CBSAs delineations issued by OMB in OMB Bulletin 23–01 for the IPPS hospital wage index beginning in CY 2025. Therefore, because the ASC wage indexes for the calendar year are the pre-floor and pre-reclassified IPPS hospital wage indexes for the fiscal year, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94362 through 94363) we finalized our proposal to incorporate the new OMB delineations into CY 2025 ASC wage indexes. We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the ASC wage index system by creating a more accurate representation of current geographic variations in wage levels. In addition to adopting the revised delineations based on OMB Bulletin No. 23–01, we also finalized our proposal to limit year-to-year ASC wage index value changes to no more than a 5-percent decrease, similar to the policy of other Medicare payment systems under Parts A and B. This 5-percent cap, implemented in a budget neutral manner through the wage index scalar, mitigates any large negative impacts of adopting the new

delineations and prevents large year-to-year declines in wage index values as a means to reduce volatility in Medicare payments.

The proposed CY 2027 ASC wage indexes reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin No. 23–01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. When all of the areas contiguous to the CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, our policy has been to determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). For CY 2026, we applied this methodology to ASCs located in CBSA 35 (Rural North Dakota) (90 FR 53911). For CY 2027, we propose to continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 35 (Rural North Dakota). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index. For CY 2027, we propose that we continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA). Further, the proposed CY 2027 ASC wage index includes our policy finalized in the CY 2025 OPPS/ASC final rule with comment period that limits wage index changes to decrease by no more than 5 percent from the final CY 2026 ASC wage index value. As we discussed in the April 2025 Update to the Ambulatory Surgical Center Payment System (Change Request 14017), to limit wage index changes by no more than 5 percent from the final CY 2026 ASC wage index, some counties may require a transition CBSA before being fully reflected in the OMB labor market delineations as set forth in OMB Bulletin No. 23–01.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2027 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

As discussed in section II.A.1.a. of this proposed rule, we are using the CY 2025 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2027 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2025, we propose to compare the estimated total payment using the CY 2026 ASC relative payment weights with the estimated total payment using the CY 2027 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2026 and CY 2027.

In consideration of our policy to provide a higher ASC payment rate with ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporated estimated total spending and estimated utilization for these codes in our budget neutrality calculation for CYs 2023 and 2024. For this proposed rule, our proposed ASC complexity adjustment codes for CY 2027 did not impact the ASC weight scalar.

Additionally, as discussed in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94361), section 4135(a) and (b) of the CAA, 2023, titled ''Access to Non-Opioid Treatments for Pain Relief'', amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary separate payments for non-opioid treatments for pain relief. As discussed in further detail in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period, for qualifying non-opioid products, we finalized applying an 18 percent payment limitation on the volume weighted payment average of the top 5 services associated with the use of the qualifying non-opioid product. In CY 2024, four of these qualifying nonopioid products were separately payable without the 18 percent payment limitation—HCPCS Codes C9089 (Bupivacaine implant, 1 mg), J0666 (Inj, bupivacaine liposome), J1096 (Dexametha opth insert 0.1 mg), and J1097 (Phenylep ketorolac opth soln). Therefore, to maintain budget neutrality, we estimated the total anticipated reduction in ASC spending for these qualifying non-opioid products for CY 2025 as a result of the 18 percent payment limitation required by section 4135 of the CAA, 2023. Based on the updated 18 percent payment limitations and CY 2025 utilization, we estimate that the proposed CY 2027 payment limitations will not impact the ASC weight scalar.

We propose to use the ratio of estimated CY 2026 to estimated CY 2027 total payments (the weight scalar) to scale the proposed ASC relative payment weights for CY 2027. The proposed CY 2027 ASC weight scalar is 0.809. Consistent with historical practice, we propose to scale, using this method (with an ASC weight scalar rounded to the nearest thousandth), the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We propose that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount, would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services or the portion of those services. The ASC payment weights for those services without predetermined national payment amounts would be scaled to eliminate any difference in the total payment between the current year and the update year.

Historically, the device portions of device-intensive procedures were not scaled so that payment for device portions would remain constant between the OPPS and ASC payment system. However, due to increased utilization of orthopedic procedures in the ASC setting, ASC expenditures on device portions of device-intensive procedures represent a substantially larger share of total ASC expenditures than in prior years. We estimate that spending attributable to device portions increased from approximately 5.4 percent of total ASC expenditures in CY 2016 to roughly 32.4 percent of total ASC expenditures in 2026. As device expenditures account for an increasingly significant share of total ASC spending, large year-to-year increases in the estimated device portions of surgical procedures require correspondingly larger reductions to the non-device portions of surgical procedures and certain ancillary services to maintain budget neutrality.

The change in the proposed ASC weight scaler for CY 2027 illustrates this effect. Specifically, the ASC weight scaler would decrease from 0.872 in CY 2026 to a proposed 0.809 in CY 2027. This reduction is largely attributable to the substantial increase in expenditures for device portions of device-intensive procedures under the ASC payment system. In turn, this increase in device portions results from the proposed budget-neutral increase in OPPS payment rates for surgical procedures that would offset the drug payment reductions associated with our proposed payment policy for 340B acquired drugs as a result of the OPPS Drug Acquisition Cost Survey.

As the ASC payment system uses the OPPS conversion factor to determine payment for the device portions of device-intensive procedures, this alters the payment relativity between services under the OPPS because the entire portion of ASC payment rates for non-device-intensive procedures is based on the lower ASC conversion factor. Because of the proposed large increase in the device portions for device-intensive procedures in CY 2027 as a result of the proposed 340B drug payment policy, we solicit comment on whether the device portions of device-intensive procedures calculated using the OPPS conversion factor should continue to be excluded from the ASC weight scaler, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scaler. We estimate that treating device expenditures for device-intensive procedures as scalable prospective expenditures would increase the proposed ASC weight scaler from 0.809 to 0.865 in CY 2027 and would reduce the device portions of device intensive procedures by approximately 14 percent.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We propose to use the CY 2025 claims data to model our budget neutrality adjustment for CY 2027.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor.

For CY 2027, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2025 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2027 ASC wage indexes. Specifically, holding CY 2025 ASC utilization, service-mix, and the proposed CY 2027 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2026 ASC wage indexes and the total adjusted payment using the proposed CY 2027 ASC wage indexes which included the 5-percent cap on wage index declines. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2026 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2027 ASC wage indexes and applied the resulting ratio of 1.0016 (the proposed CY 2027 ASC wage index budget neutrality adjustment) to the CY 2026 ASC conversion factor to calculate the proposed CY 2027 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2027 was projected to be 0.8 percentage point, as published in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496) based on IGI's 2025 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the hospital market basket update (which is the inpatient hospital market basket percentage increase reduced by the productivity adjustment) to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there was a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there were any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. At that time, the most recently available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period was within the period from CY 2019 through CY 2022. However, the impact of the COVID–19 PHE on health care

utilization, CY 2020 in particular, was tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings, when possible, to avoid possible infection from the SARS–CoV–2 virus. As a result, it was nearly impossible to disentangle the effects from the COVID–19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we needed to use claims data from a period during which the COVID–19 PHE had less of an impact on health care utilization. Therefore, for CY 2024, we finalized our proposal to extend the 5-year interim period an additional 2 years through CY 2024 and CY 2025 which we subsequently extended through CY 2026 in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53914 through 53915). We believed hospital outpatient and ASC utilization data from CYs 2023 through 2025 would enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We revised our regulations at § 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii) which establish the annual update to the ASC conversion factor, to reflect these extensions.

For this proposed rule, we propose to extend our utilization of the hospital market basket update factor in the ASC payment system for one additional year, through CY 2027, as we continue to review and evaluate hospital outpatient and ASC utilization data, as well as the migration of surgical procedures between settings. In conjunction with our proposal, we are revising our regulations at § 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii), which establish the annual update to the ASC conversion factor, the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and the productivity adjustment, to reflect this one year extension.

2. CY 2027 Proposed ASC Conversion Factor

For CY 2027, we propose to utilize the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.8 percentage point, resulting in a final hospital market basket update of 2.4 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.4 percent hospital market basket update factor to the CY 2026 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2027 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the hospital market basket update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements.

For CY 2027, we are adjusting the CY 2026 ASC conversion factor ($56.322) by a wage index budget neutrality factor of 1.0016 in addition to the productivity-adjusted hospital market basket update of 2.4 percent, discussed previously, which results in a proposed CY 2027 ASC conversion factor of $57.766 for ASCs meeting quality reporting requirements. For ASCs not meeting quality reporting requirements, we are adjusting the CY 2026 ASC conversion factor ($56.322) by the wage index budget neutrality factor of 1.0016 in addition to the reduced productivity-adjusted hospital market basket update of 0.4 percent, discussed above, which results in a proposed CY 2027 ASC conversion factor of $56.638 for ASCs not meeting the quality reporting requirements.

3. Display of the Proposed CY 2027 ASC Payment Rates and Alternative CY 2027 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2027 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the proposed CY 2027 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

The values displayed in the column titled ''Proposed CY 2027 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2027. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive- procedures; services that are paid at the PFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2027 payment rate displayed in the ''Proposed CY 2027 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2027 Payment Weight'' column was multiplied by the proposed CY 2027 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update as reduced by the productivity adjustment. The proposed CY 2027 ASC conversion factor uses the proposed CY 2027 productivity adjusted hospital market basket update factor of 2.4 percent (which is equal to the inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.8 percentage point). We also propose that if more recent data subsequently become available (for example, a more recent estimate of the inpatient hospital market basket percentage increase and the productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 ASC conversion factor in the final rule.

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2027 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2027 Payment'' column displays the proposed CY 2027 national unadjusted

ASC payment rates for all items and services. The proposed CY 2027 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are generally based on the most recently available data used for payment in physicians' offices. For CY 2021, we finalized adding a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

Addendum EE to this proposed rule provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2027.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the APC device offset percentage, the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2027 for covered surgical procedures.

XIV. Proposed Measure Removal for the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs

A. Background

We refer readers to sections XV. and XVII. of this proposed rule for program-specific background information, including statutory authority and program measure sets, regarding the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center (ASC) Quality Reporting Programs, respectively.

B. Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure in the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period where we adopted the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure into the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs (78 FR 75101 through 75102 and 78 FR 75127 through 75128), and the CY 2024 OPPS/ASC final rule with comment period where we modified the measure to align with updated clinical guidelines (88 FR 81972 through 81973 and 88 FR 82020 through 82021). The Colonoscopy Follow-Up Interval measure assesses the percentage of patients aged 45 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.[153]

When we adopted the Colonoscopy Follow-up Interval measure, we sought to address what was, at the time, the critical issue of colonoscopies potentially performed too frequently and potentially increasing patients' exposure to procedural harm.[154] [155] The measure was designed to promote adherence to recommended screening intervals through documentation of follow-up recommendations in the colonoscopy report, thereby increasing provider and patient awareness of appropriate screening intervals. Importantly, this measure assesses whether the recommended 10-year interval for a follow-up colonoscopy is documented in the colonoscopy report, rather than whether appropriate clinical care is delivered. In other words, the measure does not assess whether the follow-up colonoscopy was performed according to this recommended interval.

We continue to believe that it is important to encourage high-quality colonoscopy care in hospital outpatient departments and ASCs. We note that the Hospital Outpatient Quality Reporting Program and ASC Quality Reporting Program measure sets both currently include another measure that is tied more closely to outcomes of continued interest and importance—the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure (79 FR 66948 through 66955 and 79 FR 66970 through 66979, respectively), which assesses the incidence of hospital returns within 7 days of a colonoscopy, including emergency department visits, observation stays, and unplanned readmissions. The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure is therefore a more patient-outcome focused measure of procedure-related adverse events across both programs in contrast to the Colonoscopy Follow-Up Interval measure, which assesses documentation of recommended follow-up intervals rather than patient outcomes.[156] For these reasons, we propose to remove the Colonoscopy Follow-Up Interval measure from the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs, beginning with the CY 2027 reporting period/CY 2029 payment determination. For both programs, removal is appropriate under removal factor 6 (42 CFR 419.46(i)(3)(i)(F) and 416.320(c)(2)(vi)), the availability of a measure that is more strongly associated with a desired patient outcome for the particular topic. The Hospital Outpatient Quality Reporting Program and ASC Quality Reporting Program measure sets would continue to retain the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure.

Additionally, we continue to prioritize appropriate colonoscopy care in our other quality reporting or value-based programs. For example, we have a Colorectal Cancer Screening measure within the gastroenterology Merit-based Incentive Payment System (MIPS) Value Pathway [157] and the Medicare Shared Savings Program,[158] which assess the percentage of adults 45–75 years of age who had appropriate screening for colorectal cancer.

We invite public comment on this proposal.

XV. Hospital Outpatient Quality Reporting Program

A. Background

The Hospital Outpatient Quality Reporting Program promotes transparency and quality of care furnished at hospital outpatient departments (HOPDs). Section 1833(t)(17)(A) of the Act sets forth that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) 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 Outpatient Department fee

[153] Partnership for Quality Measurement. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. Available at *https://p4qm.org/measures/0658.*

[154] Lieberman, D. A., Faigel, D. O., Logan, J. R., Mattek, N., Holub, J., Eisen, G., Morris, C., Smith, R., & Nadel, M. (2009). Assessment of the quality of colonoscopy reports: results from a multicenter consortium. *Gastrointestinal endoscopy, 69*(3 Pt 2), 645–653. *https://doi.org/10.1016/j.gie.2008.08.034.*

[155] Goodwin, J. S., Singh, A., Reddy, N., Riall, T. S., & Kuo, Y. F. (2011). Overuse of screening colonoscopy in the Medicare population. *Archives of internal medicine, 171*(15), 1335–1343. *https://doi.org/10.1001/archinternmed.2011.212.*

[156] Partnership for Quality Measurement. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://p4qm.org/measures/2539.*

[157] CMS Quality Payment Program Reporting Requirements. Available at *https://qpp.cms.gov/reporting-requirements/measures-activities/explore-mvps/2025/M1422.*

[158] CMS Measures Inventory Tool. Colorectal Cancer Screening, Medicare Shared Savings Program. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11552&sectionNumber=1.*

schedule increase factor. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital Outpatient Quality Reporting Program. We have codified certain program requirements at 42 CFR 419.46. We also refer readers to the CMS website at *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-outpatient-quality-reporting-program* for general background on the Hospital Outpatient Quality Reporting Program, as well as the CMS QualityNet website at *https://qualitynet.cms.gov/outpatient* for current program requirements and measure specifications.

B. Hospital Outpatient Quality Reporting Program Measure Set

We refer readers to section XIV. of this proposed rule for a cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center (ASC) Quality Reporting Programs beginning with the CY 2027 reporting period/CY 2029 payment determination. We are not proposing any other changes to the Hospital Outpatient Quality Reporting Program measure set. Table 72 summarizes the previously finalized Hospital Outpatient Quality Reporting Program measure set for the CY 2028 to CY 2032 payment determinations.

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TABLE 72: PREVIOUSLY FINALIZED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
Chart-Abstracted Measures						
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*	ü	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
0661	Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival	ü	ü	ü	ü	ü
None	Left Without Being Seen	ü	ü			
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients	ü	ü			
Claims-Based Measures						
None	Abdomen CT - Use of Contrast Material	ü	ü	ü	ü	ü
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	ü	ü	ü	ü	ü
None	Breast Cancer Screening Recall Rates	ü	ü	ü	ü	ü
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	ü	ü	ü	ü	ü
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery	ü	ü	ü	ü	ü
Patient-Reported Outcomes-Based Performance Measures (PRO-PMs)						
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)	Voluntary	ü	ü	ü	ü
None	Risk-Standardized PRO–PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty	Voluntary	Voluntary	Voluntary	ü	ü

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
	(TKA) in the HOPD Setting (THA/TKA PRO-PM)					
Survey-Based Measures						
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	ü	ü	ü	ü	ü
Electronic Clinical Quality Measures (eCQMs)						
4625e	Emergency Care Access & Timeliness		Voluntary	ü	ü	ü
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM (Excessive Radiation)	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
None	ST-Segment Elevation Myocardial Infarction (STEMI)	ü	ü	ü	ü	ü

üMeasure is mandatory for the specified payment determination year.

Voluntary: Submission of this measure is optional, and HOPDs that do not report the measure are not subject to a payment reduction.

*Proposed for removal beginning with the CY 2029 payment determination.

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C. Request for Information on the Advance Care Planning Electronic Clinical Quality Measure

1. Background

We are seeking feedback on potential inclusion of an Advance Care Planning electronic clinical quality measure (eCQM) and other quality measure concepts related to advance care planning for the Hospital Outpatient Quality Reporting Program. Advance care planning is a continuous process that supports patients in understanding and communicating their goals, values, and preferences regarding future medical care and decision-making. The 1990 Patient Self-Determination Act supports advance care planning by requiring health care facilities to inform patients of their rights regarding medical decision-making and to document in the medical record whether the patient has executed an advance directive; however, it does not require that a copy of the directive itself must always be placed in the medical record.[159]

HOPDs provide care for adults with serious and complex conditions, including those receiving cancer treatment, visiting the emergency department (ED), or undergoing surgical procedures. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780 through 53786), we finalized the phase-out of the Inpatient-Only (IPO) list over a 3-year period, beginning January 1, 2026, and ending January 1, 2029. As part of the first step of the IPO phase-out, for 2026, we removed 285 HCPCS codes (mostly for musculoskeletal procedures) from the IPO list. As more procedures shift from the inpatient to the outpatient setting, complex procedures may increasingly be furnished in HOPDs. Outpatient encounters can provide repeated opportunities for clinicians to build relationships with patients over time, which may support the initiation or updating of advance care planning documentation, including when patients are relatively stable or before their illness progresses.[160] Many patients assume that their caregivers know their preferences regarding their care; however, research indicates that caregivers incorrectly predict patients' preferences approximately one-third of the time.[161] Additionally, care preferences may change over time,[162]

[159] Patient Self Determination Act of 1990. 42 U.S.C. 1395cc(f) and 1396a(w).

[160] Marshall, K. H., Riddiford-Harland, D. L., Meller, A. E., Caplan, G. A., Naganathan, V., Cullen, J., Gonski, P., Zwar, N. A., O'Keeffe, J. A., Krysinska, K., & Rhee, J. J. (2024). Feasibility and Acceptability of Facilitated Advance Care Planning in Outpatient Clinics: A Qualitative Study of Patient and Caregivers Experiences. *Journal of applied gerontology: the official journal of the Southern Gerontological Society, 43*(4), 339–348. *https://doi.org/10.1177/07334648231206742.*

[161] 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.*

[162] Mastropolo, R., Cernik, C., Uno, H., Fisher, L., Xu, L., Laurent, C. A., Cannizzaro, N., Munneke, J., Cooper, R. M., Lakin, J. R., Schwartz, C. M., Casperson, M., Altschuler, A., Kushi, L., Chao, C. R., Wiener, L., & Mack, J. W. (2024). Evolution in Documented Goals of Care at End of Life for Adolescents and Younger Adults With Cancer.

particularly in response to changes in an individual's health status or personal circumstances.[163] [164] Regular reassessment and transparent communication are essential to maintaining person-centered care. Advance care planning facilitates shared decision-making by documenting patient preferences and ensuring that care remains aligned with patients' goals across care settings and transitions.[165]

We are interested in receiving feedback on whether the Advance Care Planning eCQM is appropriate for use in the hospital outpatient setting, with or without modifications. We seek input on this and on other potential quality measures related to this topic that may be appropriate for the hospital outpatient setting.

2. Advance Care Planning Electronic Clinical Quality Measure Overview

The Advance Care Planning eCQM was proposed for adoption for the Hospital Inpatient Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, and Medicare Promoting Interoperability Programs in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568). Potentially adopting the eCQM across our quality reporting programs promotes the use of standardized advance care planning documentation in the electronic health record (EHR). Such documentation helps ensure that care remains aligned with patients' stated preferences, leverages EHRs to facilitate health information exchange, and supports the advancement of person-centered care across the care continuum.

We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568) for a complete discussion of the proposals to adopt the Advance Care Planning eCQM in certain inpatient quality reporting programs. The eCQM currently calculates the proportion of adult patients with one or more hospitalizations during the measurement period who, by the time of discharge for at least one encounter, have either an advance care planning document in the EHR or documentation of an advance care planning discussion that results in a documented decision in the patient's EHR. The numerator comprises any one of the following: (1) an 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), advance directive (or living will), or a portable medical order (medical order for life-sustaining treatment [MOLST], physician order for life-sustaining treatment [POLST], or do not resuscitate [DNR] orders); [166] or (2) documentation that an advance care planning discussion resulting in a documented decision occurred during the measurement period.[167] [168]

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 documentation of the date the advance care planning document was originally created or last updated. However, we encourage clinicians to discuss with the patient or their surrogate whether the document accurately reflects the patient's current preferences. To be considered 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 a hospital encounter in the measurement period. If a patient has multiple encounters during the measurement period, an advance care planning discussion with a decision occurring in any one of the hospital encounters during the measurement period is counted toward the numerator. The denominator includes all patients aged 18 years and older at the start of the measurement period who are discharged from a hospitalization during the 12-month measurement period. 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.[169]

There are no exclusions for the Advance Care Planning eCQM as the measure is intended to encourage advance care planning among all adult patients, recognizing that serious illness or injury can occur at any time, regardless of age or baseline health. The measure 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 including EHR data elements that include advance care planning discussions with a decision documented during a hospital encounter (including those conducted with a surrogate when the patient does not have capacity) and documentation that a patient declined or deferred advance care planning.

For more details on the Advance Care Planning eCQM, please refer to *https://www.p4qm.org/prmr-measures/muc2025-020*. We refer readers to the Electronic Clinical Quality Improvement (eCQI) Resource Center for more details on the measure specifications at (*https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1317v1*) and to the CMS QualityNet website for a list of the EHR data elements that comprise the numerator (*https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures*).

3. Solicitation for Public Comment

We are seeking input on the importance, relevance, appropriateness, and applicability of including the Advance Care Planning eCQM in the Hospital Outpatient Quality Reporting Program, as well as on other measure concepts related to advance care planning for the hospital outpatient setting. We invite public comment on the following considerations:

- Tools and measures that capture advance care planning processes and outcomes in hospital outpatient settings, including the potential future use of and modifications to the Advance Care Planning eCQM to better tailor it for the Hospital Outpatient Quality Reporting Program.
- Other approaches or measure concepts that may more effectively capture advance care planning activities in the HOPD setting.

JAMA network open, 7(12), e2450489. Available at *https://doi.org/10.1001/jamanetworkopen.2024.50489.*

[163] Shah, M. P., Wenger, N. S., Glaspy, J., Hays, R. D., Sudore, R. L., Rahimi, M., Gibbs, L., Anand, S., Tseng, C. H., & Walling, A. M. (2025). Patient-reported discordance between care goals and treatment intent in advanced cancer. *Cancer, 131*(17), e35976. Available at *https://doi.org/10.1002/cncr.35976.*

[164] 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.*

[165] 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. Available at *https://doi.org/10.1111/jgs.16801.*

[166] Some state organizations may refer to a MOLST or POLST form by other terms such as 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).

[167] Documentation that an advance care planning discussion resulting in a documented decision occurred 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 (*e.g.,* incapacitated) without requiring prior discussion with the patient.

[168] Partnership for Quality Management. Advance Care Planning. Available at *https://www.p4qm.org/prmr-measures/muc2025-020.*

[169] Partnership for Quality Management. Advance Care Planning. Available at *https://www.p4qm.org/prmr-measures/muc2025-020.*

- Relevant aspects of advance care planning for the HOPD setting, such as whether an advance care planning measure should focus on specific patient populations, higher-acuity procedures, or select departments (such as oncology, emergency department, and surgical areas).
- Timing and frequency of advance care planning, such as when and how often it should occur in the HOPD setting.
- Other measure development/re-specification ideas or opportunities for addressing advance care planning in the HOPD setting, including but not limited to changes to the current Advance Care Planning eCQM.

D. Proposed Updates to the Validation of Hospital Outpatient Quality Reporting Program Data

We refer readers to previous OPPS/ASC rulemaking [170] and 42 CFR 419.46(f) for our existing policies regarding data validation in the Hospital Outpatient Quality Reporting Program. We also refer readers to our outpatient data validation resources at *https://qualitynet.cms.gov/outpatient/data-management/data-validation/resources.*

To ensure the accuracy of Hospital Outpatient Quality Reporting Program data and the ability of interested parties to rely on such data using the provider comparison tool on *Medicare.gov* (*https://www.medicare.gov/care-compare/*), we propose to incorporate the validation of eCQM data into the Hospital Outpatient Quality Reporting Program's existing validation process as well as to streamline certain validation processes. In addition, we propose to: (1) change the validation selection pool from 500 to up to 400 hospitals; (2) clarify application of the targeting criteria to eCQMs; (3) update the number of cases for chart-abstracted and eCQM validation; (4) include eCQM validation in the timing and submission of medical record requests; (5) align the submission quarters for chart-abstracted and eCQM validation; (6) establish an eCQM validation scoring method based on data accuracy; and (7) update the educational review process for validation results. We anticipate the cumulative impact of these proposals would reduce burden for hospitals while increasing the accuracy of data reported under the program to better facilitate beneficiary decision-making and hospital quality improvement efforts.

1. Proposed Electronic Clinical Quality Measure Data Validation

To incorporate validation of eCQMs into the existing Hospital Outpatient Quality Reporting Program data validation process, we propose that validation begin with each eCQM when there is a full year of data available. For example, hospitals are required to submit all four quarters of data for the Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) eCQM beginning with data from the CY 2027 reporting period (86 FR 63837 through 63840); therefore, validation for the STEMI eCQM would begin with data from the CY 2027 reporting period. Likewise, validation for the Emergency Care Access & Timeliness (ECAT) eCQM would begin with data from the CY 2028 reporting period, which is the first year that submitting four quarters of data for this measure is mandatory (90 FR 53925 through 53934). Any future eCQMs adopted into the measure set would become eligible for validation after mandatory reporting of a full year of data is in effect, and information regarding the measures to be validated would be obtained from the CMS QualityNet website (or other CMS-designated website).

2. Proposed Changes to Selection Process for Hospital Outpatient Quality Reporting Program Validation

a. Validation Selection Pool

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74485), we finalized an annual process for the Hospital Outpatient Quality Reporting Program of selecting a random sample of 450 hospitals for validation purposes and an additional 50 hospitals based on specific targeting criteria. Since this process was finalized, we have found that hospitals randomly selected for validation generally have high accuracy rates for chart-abstracted measures and believe the number of hospitals randomly selected for validation could be reduced without impacting our ability to assess the accuracy of hospital data. At the same time, we believe that increasing the number of hospitals selected for validation based on specific targeting criteria will help to ensure data accuracy by allowing a greater number of hospitals meeting specific targeting criteria to have their data submissions reviewed for accuracy.

Therefore, we propose that, beginning with hospital selections for validation affecting the CY 2030 payment determination, up to 200 hospitals would be selected at random and up to 200 hospitals would be selected using targeting criteria, for a total of up to 400 hospitals selected for validation. As we have found consistently high agreement rates and relatively low variation among randomly selected hospitals, this change would reduce the total number of hospitals selected for validation each year from 500 to up to 400 hospitals, while maintaining a sufficiently reliable sample size. Since the total number of hospitals required to participate in validation each year would be fewer, this proposed change would also reduce overall burden for hospitals. Re-balancing the number of randomly selected hospitals compared to the number of hospitals selected by targeting criteria would also more effectively and efficiently direct validation program resources to ensure data accuracy. Beginning with validation affecting the CY 2030 payment determination, we would require any hospital selected for validation, either randomly or after meeting targeting criteria, to submit both chart-abstracted measure and eCQM data for validation. Under the current policy, hospitals selected for validation affecting the CY 2029 payment determination would continue to participate only in chart-abstracted measure validation as no eCQMs would yet be eligible for validation. Hospital selections for validation affecting the CY 2029 payment determination would continue under the existing policy. Additionally, hospitals selected for validation affecting the CY 2030 payment determination would only be required to submit eCQM data for validation when the relevant eCQM is required and eligible for validation for the applicable reporting period. This aligns with the validation process finalized for the Hospital Inpatient Quality Reporting Program, which hospitals are familiar with (85 FR 58946 through 58949). We propose to update the codified policy at § 419.46(f)(3) to reflect this proposed change.

[170] Existing validation policies were adopted for the Hospital Outpatient Quality Reporting Program in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106), CY 2012 OPPS/ASC final rule with comment period (76 FR 74484 through 74487), CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), CY 2014 OPPS/ASC final rule with comment period (78 FR 75117), CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66966), CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), CY 2021 OPPS/ASC final rule with comment period (85 FR 86185), CY 2022 OPPS/ASC final rule with comment period (86 FR 63870 through 63873), and CY 2023 OPPS/ASC final rule with comment period (87 FR 72115 through 72116).

b. Targeting Criteria for Validation Selection Pool

We have previously established several targeting criteria set forth at § 419.46(f)(3)(i) through (v):

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or
- Any hospital that has not been randomly selected for validation in any of the previous 3 years; or
- Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or
- Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an extraordinary circumstance exception (ECE) for one or more quarters.

We propose to apply the targeting criteria at § 419.46(f)(3)(i) through (v) to all measures eligible for validation in the Hospital Outpatient Quality Reporting Program, including but not limited to chart-abstracted measures and eCQMs.

3. Case Selection for Validation

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) and CY 2013 OPPS/ASC final rule with comment period (77 FR 68486), where we finalized that for each hospital selected through either random sampling or targeting criteria, we will validate up to 48 randomly selected patient cases (12 cases per quarter) from the total number of cases that the hospital successfully submitted to the CMS Clinical Data Warehouse via the Hospital Quality Reporting (HQR) system.

We propose to revise the number and distribution of cases selected for validation under the Hospital Outpatient Quality Reporting Program to ensure a balanced assessment across measure types. Specifically, we propose to validate up to 32 randomly selected patient cases for each measure, starting with validation of CY 2027 data affecting the CY 2030 payment determination. For each chart-abstracted clinical process of care measure, cases would be submitted quarterly, with up to 8 cases validated per quarter. For each eCQM, up to 32 cases would be submitted annually, allowing validation of up to 8 cases from each quarter. Table 73 illustrates these proposed changes.

TABLE 73: PROPOSED CASE SELECTION FOR VALIDATION IMPACTING CY 2029 TO CY 2031 PAYMENT DETERMINATIONS

Payment Determination Year	Reporting Period Data*	Measures Included in Validation	Number of Measures Validated	Number of Cases Validated
CY 2029	CY 2027	• Median Time from ED Arrival to ED Departure for Discharged ED Patients • Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival	2	48 cases under the current policy
CY 2030	CY 2027	• Median Time from ED Arrival to ED Departure for Discharged ED Patients • Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival • STEMI eCQM	3	Up to 96 cases under this proposal
CY 2031 (and subsequent years)	CY 2028 (and subsequent years)	• Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival • STEMI eCQM • ECAT eCQM	3	Up to 96 cases under this proposal

* We refer readers to section XV.D.5.c. of this proposed rule for our proposal to shift the payment impact of validation from 2 years after the reporting period to 3 years after the reporting period.

We believe this approach would support a more balanced and representative assessment of data accuracy across both chart-abstracted measures and eCQMs. We further believe that broadening the selection of cases across measure types, rather than concentrating cases within a single measure, would improve our ability to detect potential data inaccuracies and systemic reporting issues.

Under this proposed validation policy, all hospitals selected for validation purposes would receive a total of five medical record requests for complete supporting medical record documentation from CMS or its designated contractor: four quarterly requests containing randomly selected chart-abstracted cases and one annual request containing randomly selected eCQM cases. We refer readers to § 482.24(c) for a definition of what is expected in a medical record submitted for validation.

4. Timing and Electronic File Submission for Medical Records Requests

a. Chart-Abstracted Measures

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870 through 63871) and § 419.46(f)(1) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests and the time period for data validation, including the deadlines for submitting medical records to CMS. We are not proposing any changes affecting the time period or deadlines for electronic file submission for chart-abstracted measures under our validation policy.

b. Electronic Clinical Quality Measures

Under this proposal, we would apply the same electronic file submissions policy to eCQM medical records requests in alignment with the chart-abstracted measures that hospitals are already familiar with. Upon written request by CMS or its contractor, a hospital would be required to submit portable document format (PDF) copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process (currently, Unified File Management [UFM]/Managed File Transfer [MFT]). A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date on the written request. We would continue to reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

5. Submission Quarters

a. Background

Currently, hospitals selected for chart-abstracted validation are required to submit data from 2 years prior to the applicable CY payment determination year, consisting of validation quarter 1 (January 1 through March 31), validation quarter 2 (April 1 through June 30), validation quarter 3 (July 1 through September 30), and validation quarter 4 (October 1 through December 31) (80 FR 70524).

Under our proposed validation policy, hospitals selected for eCQM validation for a given payment determination year would be required to submit data from the calendar year that is 3 years prior to the applicable payment determination year because eCQM data are reported annually rather than quarterly. A 3-year cycle allows sufficient time to complete sampling, medical record abstraction, confidence interval calculation, educational reviews, and quality assurance prior to payment determination.

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, we would shift the payment impact of validation from 2 years after the reporting period to 3 years after the reporting period. During this transition, the validation results for CY 2027 chart-abstracted data would affect both the CY 2029 and the CY 2030 payment determination, as detailed below.

b. Validation Affecting the CY 2029 Payment Determination

To maintain the continuity of annual validation activities while we shift to a 3-year cycle, CY 2027 chart-abstracted data would continue to be used for the CY 2029 payment determination under the existing 2-year cycle in accordance with existing policy for chart-abstracted measure validation. In other words, there will be no change from our current policy for the CY 2029 payment determination.

c. Validation Affecting the CY 2030 Payment Determination

For the CY 2030 payment determination, CY 2027 chart-abstracted data would be used again in combination with CY 2027 eCQM data for validation. That is, validation results for CY 2027 chart-abstracted data would impact both the CY 2029 and CY 2030 payment determinations. Table 74 illustrates our proposed changes, including a transition year, to align the validation for chart-abstracted and eCQM data.

TABLE 74: PREVIOUSLY FINALIZED AND PROPOSED VALIDATION PROCESS FOR CY 2029 TO CY 2031 PAYMENT DETERMINATIONS

Payment Determination Year	Reporting Period Data	Data Type	Validation Cycle	Notes
CY 2029	CY 2027	Chart-abstracted	Current: 2-years between reporting period and payment determination	Continues current policy to maintain annual validation continuity.
CY 2030	CY 2027	Chart-abstracted and eCQM	Proposed: 3-years between reporting period and payment determination	Supports transition to combined validation process. CY 2027 chart-abstracted data are used again for CY 2030 payment. This overlap ensures no gap in annual validation activities during the transition.
CY 2031 (and subsequent years)	CY 2028 (and subsequent years)	Chart-abstracted and eCQM	Proposed: 3-years between reporting period and payment determination	Steady state begins after transition year.

For the transition year affecting the CY 2030 payment determination, we propose a one-time modification of the hospital selection and targeting methodology such that hospitals selected for validation based on CY 2027 data, affecting the CY 2029 payment determination, would not be selected again, either randomly or through targeted selection, for validation of the same data affecting the CY 2030 payment determination. For example, we would not automatically reselect a hospital that failed to meet the validation requirements for the CY 2029 payment determination under the targeting criterion at § 419.46(f)(3)(i) for validation affecting the CY 2030 payment determination. This approach is intended to eliminate the potential burden to hospitals that would have gone through the validation process for the CY 2029 payment determination while allowing validation activities to continue during the transition year.

d. Validation Affecting the CY 2031 Payment Determination and for Subsequent Years

As seen in Table 74, following the transition period, we would adopt a 3-year validation cycle, under which validation results for an annual reporting period would be applied to the applicable payment determination 3 years later. That is, beginning with CY 2028 chart-abstracted and eCQM data, validation results would impact the payment determination 3 years following the reporting period, which for CY 2028 reporting period data is the CY 2031 payment determination. Following the transition year, we would proceed with validation policies under the 3-year validation cycle, including the use of aligned data submission periods and the application of established hospital selection and targeting methodologies. We believe aligning the quarters of submission data used for both chart-abstracted measures and eCQM validation would allow hospitals selected for validation to more easily track and meet validation requirements.

6. Scoring Method

a. Chart-Abstracted Measures

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72103 through 72106), we finalized the calculation of validation scores under the Hospital Outpatient Quality Reporting Program using the upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level. We are not proposing any changes to this threshold.

b. Electronic Clinical Quality Measures

We propose that eCQM validation scores would be determined using the same methodology currently used to score chart-abstracted measure validation, such that eCQM validation scoring would be based on the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted to CMS), beginning with CY 2027 eCQM data affecting the CY 2030 payment determination. Consistent with the data validation scoring threshold currently applied to chart-abstracted measures and codified at § 419.46(f)(2), a minimum score of 75 percent accuracy would be required for the hospital to pass the eCQM validation requirement. Applying an upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level is appropriate because it accounts for sampling variability, reflects a reasonable standard of data accuracy, and aligns with existing validation thresholds for chart-abstracted measures while allowing for legitimate differences in hospital data implementation.

To incentivize the timely and complete submission of requested medical records, we propose that any missing medical records would be treated as mismatches, beginning with the validation of the CY 2027 eCQM data affecting the CY 2030 payment determination and for subsequent years. Because mismatches would count against the agreement rate, treating any missing medical records as mismatches would encourage submission of complete medical records and disincentivize selective medical record submissions. We note that this approach is consistent with our existing policy for chart-abstracted measure validation, under which missing records are treated as mismatches.

Using this approach, at the end of each calendar year, we would compute an eCQM confidence interval using the results of all four quarters to determine the final eCQM validation score. Hospitals' submitted eCQM data and the

submitted medical records would be used to compute an agreement rate and the associated confidence interval around the score. The upper bound of the 90 percent two-sided confidence interval would be used as the final eCQM validation score for the selected hospital. We would then compare this final validation score to the 75 percent accuracy threshold described below to determine whether the hospital meets the eCQM validation requirement. Data validation scoring is at the measure level, not the individual data element level. If CMS or its contractor does not reach the same outcome as the hospital's original submission, then the case may be considered a mismatch. We selected 75 percent as the threshold for the validation score because we believe this level is reasonable to reflect accurate performance, but still realistic for hospitals to achieve. It also allows for legitimate differences in how hospitals implement measures and map their data. We note we adopted the same eCQM scoring method for the Hospital Inpatient Quality Reporting Program (89 FR 69574 through 69577).

c. Annual Payment Update

Beginning with the validation of CY 2027 data affecting the CY 2030 payment determination, hospitals would receive two validation scores: one for chart-abstracted measure data and one for eCQM data. As we finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66873 through 66874), a hospital that does not meet validation requirements will not receive the full annual payment update under the OPPS. Therefore, if a hospital does not meet either chart-abstracted validation requirements or eCQM validation requirements, we propose the hospital would not receive the full OPPS annual payment update. In other words, to be eligible for a full annual payment update, provided all other Hospital Outpatient Quality Reporting Program requirements are met, a hospital selected for validation would need to attain at least a 75 percent validation score for chart-abstracted measure validation and at least a 75 percent validation score for eCQM data validation. We also propose to codify this policy by updating the regulatory text at § 419.46(f)(2).

7. Educational Review Process

a. Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86185) where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. We also refer readers to § 419.46(f)(4) for our policies regarding the educational review process, including validation score review and correction, for chart-abstracted measures. As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), for CY 2020 and subsequent years, if a hospital requests an educational review for any of the first three quarters of validation and this review yields incorrect CMS validation results for chart-abstracted measures, the corrected quarterly score will be used to compute the final confidence interval.

We propose to revise our policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval, beginning with the CY 2030 payment determination. Under our current policy, due to time constraints, educational reviews for the final quarter of data are not completed in time to affect validation results, and hospitals must use the reconsideration process. Under the proposal to extend the validation timeline from a 2-year cycle to a 3-year cycle, sufficient time would become available to complete educational reviews for all four quarters. As a result, any corrected scores from educational reviews across all quarters would be used in calculating the final confidence interval.

b. Electronic Clinical Quality Measures

We propose extending the educational review process established for chart-abstracted measure validation to eCQM validation beginning with validation affecting the CY 2030 payment determination (that is, starting with validated data from CY 2027). We believe that expanding the educational review process to include eCQMs would allow hospitals to better understand the processes and data for eCQM validation.

Hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation of eCQMs. A hospital would have 30 calendar days following receipt of the validation results to contact CMS' Validation Support Contractor requesting a written explanation of its performance. Because hospitals receive eCQM validation results on an annual basis, they would have the opportunity to request an educational review once annually. Upon receipt of an educational review request, we would review the requested data elements and written justifications provided by the hospital. We would also provide the results of the eCQM validation educational review to the requesting hospital, including our findings of whether the scores were correct or incorrect, through a CMS-approved secure file transmission process (currently, UFM/MFT). If the results of a validation educational review determine that the original validation score was incorrect, the corrected score would be used to compute the final validation score and confidence interval at the end of each calendar year.

We propose to codify this policy by revising § 419.46(f)(4) to include eCQMs. As proposed, § 419.46(f)(4) would indicate that hospitals selected for validation may request an educational review within 30 calendar days from the date validation results are made available. Under the proposed revisions to § 419.46(f)(4), if the results of an educational review indicate one or more measures were incorrectly scored, the corrected validation score will be used to compute the final validation score used for payment determination. Refer to section XXIV.A. of this proposed rule for more information on the burden estimates associated with these proposals.

We invite public comment on the proposed changes regarding data validation in the Hospital Outpatient Quality Reporting Program, including incorporating eCQM validation into the existing validation process for chart-abstracted measures, reducing the validation selection pool from 500 to up to 400 hospitals, updating the number of cases for chart-abstracted and eCQM validation, transitioning from a 2-year to a 3-year cycle between the reporting period and the payment determination year, establishing the eCQM validation scoring method, and expanding the educational review process to include eCQM validation.

E. Proposed Updates to the Hospital Outpatient Quality Reporting Program Validation Reconsiderations and Appeals Procedures

1. Reconsiderations and Appeals

We refer readers to § 419.46(g) for our reconsideration and appeals procedures. Under our existing requirements at § 419.46(g)(2)(vii), hospitals submitting reconsideration requests are required to submit a copy of all materials that the hospital submitted to comply with the requirements of the affected payment determination year. In the CY 2022 OPPS/ASC final rule with comment

period, we finalized a requirement for hospitals to submit only electronic files rather than paper copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination and for subsequent years (86 FR 63871).

2. Proposed Removal of the Re-Submission of Supporting Medical Documentation for Validation Reconsideration Requests

With the transition to all electronic submission of copies of medical records for Hospital Outpatient Quality Reporting Program data validation, the current reconsideration requirement to resubmit records used for validation results in a validation-related reconsideration request is no longer necessary and creates duplicative files and administrative burden. We note the Hospital Inpatient Quality Reporting Program finalized a policy in the FY 2025 IPPS/LTCH PPS final rule with comment period to remove the requirement to resubmit medical records as part of their request for reconsideration of a validation determination beginning with CY 2023 discharges affecting the FY 2026 payment determination (89 FR 69577).

We propose to revise existing § 419.46(g)(2)(vii) and (viii) of our regulations to no longer require hospitals to resubmit materials previously submitted to CMS for validation reconsideration requests, unless specifically requested by CMS, and to require only that the hospital provide any evidence supporting its validation reconsideration request. Under this proposal, hospitals that need to submit a revised medical record may still do so, but those hospitals that would otherwise be submitting copies of previously submitted records would no longer be required to submit them. Removing resubmission of medical documentation as a requirement for validation reconsideration would reduce administrative burden for most hospitals that do not have revised records to submit, as well as for CMS to collect and track medical records that are already available. Please refer to section XXIV.A.5. of this proposed rule for more information on the burden estimates associated with this proposed removal.

We invite public comment on this proposal to remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination. We also propose to codify this policy by updating the regulatory text at § 419.46(g).

F. Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2027 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0-percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the internet on the CMS website): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS/ASC final rule with comment period, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update, and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD

update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2027

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2027 annual payment update factor. For the CY 2027 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $102.004, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $100.015. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1,'' ''J2,'' ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' and ''U'' (other than New Technology APCs to which we have proposed status indicator assignments of ''S'' and ''T''). We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we propose to continue to calculate the reporting ratio to four decimals.

XVI. Rural Emergency Hospital (REH) Quality Reporting Program

The Rural Emergency Hospital (REH) Quality Reporting Program, implemented under section 1861(kkk)(7) of the Act, ensures transparency and quality for rural emergency hospitals (REHs), defined at section 1861(kkk)(2) of the Act. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82046 through 82047) for a detailed discussion of the history of the REH Quality Reporting Program. The REH Quality Reporting Program requirements are codified at 42 CFR 419.95. We also refer readers to the CMS QualityNet REH Quality Reporting Program website at *https://qualitynet.cms.gov/reh/rehqr* for current program requirements and measure specifications. We are not proposing any changes to the REH Quality Reporting Program in this proposed rule.

XVII. Ambulatory Surgical Center Quality Reporting Program

A. Background

The Ambulatory Surgical Center (ASC) Quality Reporting Program promotes transparency regarding the quality of care provided at ASCs. Section 1833(i)(7)(A) of the Act authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0 percentage points for such year that an ASC fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory authority of the ASC Quality Reporting Program. We have codified certain ASC Quality Reporting Program requirements at 42 CFR part 416, subpart H (§§ 416.300 through 416.330). We also refer readers to the CMS website at *https://www.cms.gov/medicare/quality/initiatives/asc-quality-reporting* for general background on the ASC Quality Reporting Program and to the CMS QualityNet ASC Quality Reporting Program website at *https://qualitynet.cms.gov/asc* for current program requirements and measure specifications.

B. ASC Quality Reporting Program Measure Set

We refer readers to section XIV. of this proposed rule for a cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

measure from the ASC Quality Reporting and Hospital Outpatient Quality Reporting Programs beginning with the CY 2027 reporting period/CY 2029 payment determination. We are not proposing any other changes to the previously finalized ASC Quality Reporting Program policies in this proposed rule.

Table 75 summarizes the previously finalized ASC Quality Reporting Program measure set for the CY 2028 to CY 2032 payment determinations.

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TABLE 75: PREVIOUSLY FINALIZED ASC QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
	Chart-Abstracted Measures					
None	All-Cause Hospital Transfer/Admission	ü	ü	ü	ü	ü
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*	ü	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
None	Normothermia Outcome	ü	ü	ü	ü	ü
None	Patient Burn	ü	ü	ü	ü	ü
None	Patient Fall	ü	ü	ü	ü	ü
None	Unplanned Anterior Vitrectomy	ü	ü	ü	ü	ü
None	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	ü	ü	ü	ü	ü
	Claims-Based Measures					
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	ü	ü	ü	ü	ü
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (ASCs)	ü	ü	ü	ü	ü
3366	Hospital Visits After Urology ASC Procedures	ü	ü	ü	ü	ü
3470	Hospital Visits After Orthopedic ASC Procedures	ü	ü	ü	ü	ü
	Patient-Reported Outcomes-Based Performance Measures					
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)	Voluntary	Voluntary	Voluntary	ü	ü
	Survey-Based Measures					
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	ü	ü	ü	ü	ü

üMeasure is mandatory for the specified payment determination year.
Voluntary: Submission of this measure is optional, and ASCs that do not report on the measure are not subject to a payment reduction.
* Proposed for removal beginning with the CY 2029 payment determination.

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C. Request for Information on Stratification of the All-Cause Transfer/Admission Measure

We previously adopted the All-Cause Transfer/Admission measure in the ASC Quality Reporting Program in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499). The All-Cause Transfer/Admission measure is an outcome measure that assesses the rate of patients receiving care in an ASC who require transfer to a hospital or admission to a hospital upon discharge from the ASC. Currently, the measure does not distinguish the phase of care in which a transfer occurs (pre-procedure, intra-procedure, or post-procedure).[171]

As reported in MedPAC's 2025 Report to Congress, extracapsular cataract removal with intraocular lens insertion was the most common Medicare Fee-for-Service procedure performed by ASCs in 2023, accounting for 19 percent of all ASC Fee-For-Service volume. In addition, a substantial number of ASCs that bill Medicare specialize in a single clinical area, with gastroenterology and ophthalmology among the most common specialties providing services to Medicare beneficiaries.[172] A recent retrospective study which examined the causes and timing of direct hospital transfers from an ophthalmology-specific surgery center over a 2-year period reported that about 77 percent of hospital transfers were associated with concerns identified prior to the induction of anesthesia, including transfers identified in the preoperative area or upon connection to monitoring equipment in the operating room.[173] Nearly 23 percent of these transfers were directly related to anesthesia or the surgical procedure, including events occurring during induction or intraoperatively. These findings suggest that the majority of hospital transfers from ophthalmology-specific ASCs could be occurring preoperatively rather than procedural complications. While many of these events occur prior to anesthesia induction, they are often identified during anesthesia-led pre-procedure evaluation, reflecting important safety checks in patient assessment.[174]

Based on these findings and discussions with interested parties, we are considering whether adding a phase of care stratification relative to the surgical encounter (for example, pre-procedure, intra-procedure, and post-procedure) could improve the interpretability and usefulness of the All-Cause Transfer/Admission measure in the ASC Quality Reporting Program. The current measure reports an overall rate of transfers/admissions and does not specify when during the ASC encounter the need for transfer/admission is identified. Stratification by phase of care would improve attribution and interpretability across the diverse range of ASC services, including non-operative procedures such as those associated with pain management, for hospital transfers/admissions associated with ASC care.

It is important to measure and monitor transfers/admissions that occur pre-procedure, intra-procedure, and post-procedure, as each stratum could provide insight into care processes between facilities. Pre-procedure events may reflect the effectiveness of pre-operative evaluation, patient selection, and escalation or transfer processes, while intraoperative and post-procedure events may be more closely associated with anesthesia administration, the procedure itself, and immediate recovery, including complications that arise during or after the ASC encounter. A phase of care stratification may also provide more comprehensive information to support beneficiary decision-making and patient safety monitoring.

We seek public comment on clinically meaningful and operationally feasible approaches for incorporating a phase of care stratification for the All-Cause Transfer/Admission measure. Specifically, we seek input on potential stratification frameworks, including appropriate time anchors, their operational definitions, and the corresponding time windows that could be used to define each stratification category.

D. Form, Manner, and Timing of Data Submission

We refer readers to prior OPPS/ASC final rules with comment period and § 416.310 for information regarding the data submission and reporting requirements for claims-based,[175] survey-based,[176] web-based [177] (that is, data submitted via a CMS-designated information system), and patient-reported outcome-based performance

[171] Partnership for Quality Measurement. All-Cause Hospital Transfer/Admission. Available at *https://p4qm.org/measures/0265.*

[172] MedPac. (2025). Report to the Congress: Medicare Payment Policy-Ambulatory Surgical Center Services: Status Report. Available at *https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch10_MedPAC_Report_To_Congress_SEC.pdf.*

[173] Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery: insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery, 51*(5), 376–381. *https://doi.org/10.1097/j.jcrs.0000000000001613.*

[174] Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery: insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery, 51*(5), 376–381. *https://doi.org/10.1097/j.jcrs.0000000000001613.*

[175] We refer readers to §§ 416.310(a) and (b) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534 through 70536) for information regarding the claims-based measure data submission and reporting requirements.

[176] We refer readers to § 416.310(e) and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63905 through 63909) for information regarding the survey-based data submission and reporting requirements.

[177] We refer readers to § 416.310(c)(1) and the CY 2025 OPPS/ASC final rule with comment period (89 FR 94435 and 94436) for details regarding submission of web-based data via a CMS-designated information system (currently the Hospital Quality Reporting (HQR) system).

measures [178] in the ASC Quality Reporting Program. We maintain measure technical specification manuals (referred to as Specifications Manuals) that can be found on the CMS website at *https://qualitynet.cms.gov/asc/specifications-manuals.*

We are not proposing any changes to these policies in this proposed rule.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2027, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update was the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional 2 years (through CY 2025) in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81960). In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53915), we extended the interim period an additional year (through CY 2026). As discussed in section XIII. of this proposed rule, we propose to continue using the productivity-adjusted hospital market basket update as the update factor for the ASC payment system for CY 2027. Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update conversion factor; (2) to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination; and (3) that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment. The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the internet on the CMS website): ''A2'', ''D2'', ''G2'', ''P2'', ''R2'', and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''D2'', ''G2,'' ''J8'', ''P2'', ''R2'', and ''Z2.'' These services include separately payable drugs, biologicals, and radiopharmaceuticals, skin substitute supplies, software-as-a-service codes, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services, and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to

[178] We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82041 through 82045) for information regarding the patient-reported outcome-based performance measure data submission and reporting requirements.

which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2026 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We propose to continue applying these policies for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

XVIII. Accrediting Organization (AO) Deeming Authority for the Emergency Medical Treatment and Labor Act (EMTALA)

A. Background

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted in 1986 and codified as section 1867 of the Act (42 U.S.C. 1395dd) to address concerns regarding the inappropriate transfer of, or refusal to treat individuals with emergency medical conditions who are seeking emergency department care, commonly referred to as ''patient dumping.'' EMTALA applies to hospitals that participate in Medicare and operate emergency departments, including critical access hospitals (CAHs) and rural emergency hospitals (REHs). For purposes of this discussion, the term ''hospitals'' includes CAHs and REHs. To enroll and participate in Medicare under section 1866(a)(1)(I) of the Act (42 U.S.C. 1395cc(a)(1)(I)), all such hospitals must agree to comply with EMTALA's statutory and regulatory requirements.

Section 1867 of the Act establishes the three core obligations of EMTALA. First, when an individual comes to a hospital's emergency department and requests examination or treatment, the hospital must provide an appropriate medical screening examination to determine whether an emergency medical condition exists. Second, if the hospital determines that the individual has an emergency medical condition, the hospital must provide either necessary stabilizing treatment within its capability or arrange for an appropriate transfer to another medical facility. Third, hospitals with specialized capabilities or facilities shall not refuse to accept appropriate transfers of individuals requiring such capabilities or facilities if the receiving hospital has the capacity to treat the individual. The statute also authorizes the imposition by the Office of Inspector General (OIG) of civil monetary penalties and, for physicians, exclusion from participation in Federal health care programs for violations, and permits the Centers for Medicare & Medicaid Services (CMS) to impose termination of a hospital's Medicare provider agreement for non-compliance in accordance with 42 CFR 489.53.

CMS has implemented EMTALA through regulations at 42 CFR 489.20 and § 489.24, which address two distinct categories of obligations. Section 489.20(*l*), (m), (q) and (r) sets forth administrative requirements, including to post EMTALA signage, maintain a central log of individuals who present to the emergency department, retain transfer records for 5 years, and maintain an on-call physician list. These administrative obligations support transparency, documentation, and accountability in emergency care operations. These requirements are provider agreement commitments, and obligations hospitals accept as a condition of Medicare participation under section 1866(a)(1)(I) of the Act. They are distinct from the substantive individual care protections at § 489.24.

Section 489.24 implements the statute's substantive protection requirements for individuals who present to the emergency department and request examination or treatment, including detailed provisions governing the provision of medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities. These requirements reflect the core protections established by section 1867 of the Act and are directly enforceable by CMS and/or the Office of Inspector General (OIG).

Enforcement of EMTALA has historically occurred through complaint investigations conducted by State Survey Agencies (SAs) under CMS direction. However, hospitals may also participate in Medicare via accreditation from a CMS-approved accrediting organization (AO) under section 1865(a)(1)(A) of the Act and implementing regulations at 42 CFR part 488. Pursuant to § 488.6, CMS ''deems'' a hospital to meet Medicare requirements if it is accredited by an AO with a hospital accreditation program approved by CMS. CMS will approve such organizations if it finds that its standards and survey processes provide reasonable assurance that accredited entities meet or exceed applicable Medicare requirements. Hospitals accredited by such AOs are deemed to meet the Medicare CoPs but are subject to CMS validation surveys and complaint investigations in accordance with existing CMS policies and procedures. More than 90 percent of Medicare-participating hospitals (excluding CAHs and REHs) and more than 40 percent of CAHs, independent of hospitals, are accredited by AOs with CMS-approved accreditation programs. At this time, no REHs are deemed to meet requirements through a CMS-approved accreditation program.

We propose that if an AO identifies EMTALA deficiencies at § 489.24 during an accreditation or reaccreditation survey, the matter would have to be referred to the CMS location for further review and possible SA investigation. If an AO identifies EMTALA deficiencies at § 489.20(*l*), (m), (q) and (r), they would require the hospital or CAH to submit an acceptable Plan of Correction (PoC) addressing how it would come into compliance with the cited EMTALA requirements. If the PoC is accepted and the hospital has returned to compliance, then no further enforcement action would be taken. If the PoC is rejected, the AO would be required to contact the CMS location for further review. Under § 488.5(a)(4)(ix), accreditation organizations are already required to timely notify CMS if an AO survey identifies an ''immediate jeopardy''; the proposed EMTALA requirement would augment the already-existing reporting requirement. If a complaint alleging an EMTALA violation is received by CMS (or the SA acting under an agreement pursuant to section 1864 of the Act), it would be triaged to determine its investigation priority level. The SA or CMS conducts an onsite investigation and if a violation is identified, a deficiency is cited and the survey findings documented. Currently the SA refers § 489.24 violations to the OIG, which has independent statutory authority to impose civil money penalties and potential exclusion of physicians from Federal health care programs. CMS retains the authority to terminate a hospital's Medicare provider agreement

for EMTALA noncompliance at § 489.53.

In CY 2025, we issued 1,071 EMTALA citations for violations of the two applicable regulations, underscoring the need for Medicare-participating hospitals to comply with emergency care obligations. Of these, 521 citations were issued under § 489.20 requirements, 530 citations were issued under § 489.24, the more expansive regulation that governs the specific medical screening, stabilization, and transfer requirements hospitals must fulfill when an individual presents to a dedicated emergency department and requests examination or treatment, and 20 citations were issued under both § 489.20 and § 489.24. Administrative compliance under § 489.20 appears to be a leading indicator of overall EMTALA program integrity. A hospital that cannot maintain accurate on-call logs, post required notices, or retain transfer documentation is a hospital whose broader EMTALA compliance posture warrants closer scrutiny. Incorporating a structured, thorough review of § 489.20 requirements into every hospital survey is essential to fulfilling the protective intent of EMTALA. The incorporation of the requirements at § 489.20(*l*), (m), (q) and (r) into the accreditation and reaccreditation survey process mean that AOs would assess whether hospitals are maintaining the documentation, recordkeeping, and operational safeguards that support transparency and accountability in emergency care. Because these obligations are record-based and procedural, we propose to review AO survey processes as part of our hospital accreditation program approval to check that EMTALA requirements are included within the existing accreditation framework.

This proposal does not alter the existing framework governing CMS' disclosure of accreditation survey findings. Under section 1865(b) of the Act, the Secretary is prohibited from disclosing any accreditation survey released to the Secretary and conducted by a CMS-approved AO, unless the survey and information related to such a survey relates to an enforcement action or to a home health agency or hospice program survey. Accordingly, most accreditation survey reports submitted by CMS-approved AOs are not subject to the same government disclosure requirements as SA-conducted surveys. However, the statute does not prohibit the AO itself or a client hospital from disclosing its own survey findings.

It should be noted that findings related to potential § 489.24 violations must be referred to CMS for SA investigation and those findings would continue to follow existing public disclosure procedures applicable to complaint-based SA investigations, which are separate from AO accreditation survey reports. Section 1865(b) of the Act explicitly permits the Secretary to publicly disclose AO surveys and information related to them to the extent that such surveys and information relate to an enforcement action taken by the Secretary.

Our regulations at 42 CFR part 488 govern AO approval and oversight. The proposal described in this rule would operate within section 1865 of the Act and part 488 statutory and regulatory structures by integrating review of EMTALA's administrative requirements into existing accreditation organization processes for accrediting and re-accrediting hospitals, while preserving CMS and OIG enforcement authority over EMTALA's core statutory protections under section 1867 of the Act. We anticipate several benefits associated with this proposal. First, integrating EMTALA administrative review into accreditation and state certification surveys would minimize operational disruption for hospitals. Rather than undergoing separate review processes triggered by administrative deficiencies, hospitals would address these requirements within the structured accreditation survey framework.

Second, this policy may improve compliance consistency with the documentation and operational safeguards at § 489.20(*l*), (m), (q) and (r). Because these requirements are record-based and procedural in nature, they are well-suited to routine survey evaluation. Regular review during accreditation surveys may enhance sustained compliance.

Third, this proposal would free SAs from needing to carry out EMTALA-only initial investigations, and allow such SAs to concentrate more resources on complaint-based investigations involving potential violations of § 489.24, including issues related to appropriate medical screening examinations, stabilizing treatment, and appropriate transfers. These investigations often require case-specific fact-finding and clinical review, and preserving SA capacity for these activities supports effective enforcement of EMTALA's core protections.

B. CMS Approval of Accreditation Organizations

We propose to clarify at § 488.5(a) that an AO with CMS-approved accrediting programs for hospitals under section 1865 of the Act may assess compliance with the EMTALA-related administrative requirements set forth at § 489.20(*l*), (m), (q) and (r) as part of their initial accreditation and reaccreditation surveys for those provider types. This proposal is limited to AOs conducting initial accreditation or reaccreditation surveys within the scope of their existing CMS-approved accrediting programs. This amendment would formally require CMS-approved AOs to incorporate review of these specified EMTALA obligations into the existing accreditation framework, while preserving CMS' direct enforcement authority over EMTALA's core statutory protections.

Under this proposal, AOs would evaluate hospital compliance with the administrative commitments codified at § 489.20(*l*), (m), (q) and (r), including requirements to post appropriate EMTALA signage; maintain a central log of individuals who present to the emergency department; retain transfer records for a period of 5 years; and maintain an on-call physician list to ensure availability of specialty services. These obligations are documentary and administrative in nature, are well-established in regulation, and are conducive to structured review within the context of accreditation and reaccreditation surveys.

If an AO identifies noncompliance with any of the EMTALA administrative requirements at § 489.20(*l*), (m), (q) and (r), the AO would cite the deficiency and address it through its established procedures, consistent with the procedures it used to address other Medicare deficiencies identified during accreditation and reaccreditation surveys. This would include requiring corrective action plans, monitoring compliance, and reporting findings to CMS in accordance with existing oversight and validation protocols. CMS would retain ultimate oversight responsibility and could take additional action as appropriate under its survey and enforcement authorities.

Importantly, this proposal would not authorize AOs to assess or enforce compliance with the EMTALA requirements at § 489.24. CMS and OIG would retain enforcement authority over those provisions, including obligations related to medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities. If an AO

identified potential noncompliance with § 489.24 during an initial accreditation or reaccreditation survey, the AO would be required to refer the matter to CMS for further review and possible SA investigation, consistent with existing procedures outlined in the CMS State Operations Manual (SOM) Chapter 5, ''Complaint Procedures.'' In addition, the OIG would continue to exercise its statutory authority under section 1867(d) of the Act to impose civil monetary penalties or exclusion, as applicable. CMS would also retain authority to terminate a hospital's Medicare provider agreement for EMTALA violations under section 1866(b)(2) of the Act and § 489.53.

We believe that the administrative requirements at § 489.20(*l*), (m), (q) and (r) are appropriate for evaluation during initial accreditation and reaccreditation surveys. Integrating review of these provisions into the AO survey process would promote more consistent monitoring of established documentation and recordkeeping obligations, reduce duplicative investigations triggered solely by administrative concerns, and minimize disruption to hospital operations. At the same time, this approach would allow SAs to concentrate their resources on complaint-based investigations involving potential violations of § 489.24.

To implement this proposal, we would revise § 488.5(a) by adding a new paragraph (21), laying out the AO's responsibility to incorporate the EMTALA administrative requirements into its accreditation standards and survey processes and to identify and address noncompliance with those provisions within the deeming framework.

C. Evaluation of Accreditation Authority Request

In § 488.5, we propose to add a new paragraph (a)(21) to integrate review of the EMTALA administrative requirements at § 489.20(*l*), (m), (q) and (r) into the existing hospital accreditation deeming framework.

Under this proposal, AOs with a CMS-approved accrediting program for hospitals would be required to assess compliance with the § 489.20(*l*), (m), (q) and (r) administrative requirements including required signage display, maintenance of an emergency department log, retention of transfer records, and maintenance of an on-call physician list as part of their accreditation and reaccreditation surveys. AOs would have to document the procedures used to assess compliance with these requirements and would be required to cite and address any identified deficiencies through their established accreditation procedures, consistent with the procedures used to address Medicare deficiencies identified during accreditation and reaccreditation surveys.

XIX. Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services''.[179] As part of the CY 2021 OPPS/ASC final rule with comment period, we added two additional service categories to the prior authorization process for certain hospital OPD services (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPS/ASC final rule with comment period, we added one more service category to the prior authorization process for certain hospital OPD services (87 FR 71748, 72224 through 72233). The regulations governing the prior authorization process for certain hospital OPD services are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89, with the specific service categories listed in § 419.83.

Section 419.83(a)(1) lists the specific service categories for which prior authorization must be obtained for service dates on or after July 1, 2020: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. Section 419.83(a)(2) lists two additional service categories for which prior authorization must be obtained for service dates on or after July 1, 2021: cervical fusion with disc removal, and implanted spinal neurostimulators. Section 419.83(a)(3) lists Facet Joint Interventions as an additional service category for which prior authorization must be obtained for service dates on or after July 1, 2023. Section 419.83(b) states that CMS will adopt the list of hospital outpatient department service categories requiring prior authorization, and any updates or geographic restrictions, through formal notice-and-comment rulemaking. Section 419.83(c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and § 419.83(d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

[179] See also correction notice issued January 3, 2020 (85 FR 224).

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

In accordance with § 419.83(b), we propose to expand prior authorization requirements to include additional Botulinum Toxin Injection services. The eight additional Botulinum Toxin Injection codes would be incorporated into the existing list at proposed revised § 419.83(a)(2) and would require prior authorization for services provided on or after July 1, 2027. Additionally, to improve readability and brevity, we propose to remove effective date language from the regulatory text and revise the section numbering. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) would be renumbered as (a)(1) through (8).

1. Expansion of Service Category

We propose that additional Botulinum Toxin Injection codes that would require prior authorization beginning on July 1, 2027, are those identified by the HCPCS codes in Table 76. For ease of reference, in Table 77 we have included the 2020 Final List of Outpatient Services that Require Prior Authorization for the five initial service categories, the 2021 Final List of Outpatient Services that Require Prior Authorization for two additional service categories, and the 2023 Final List of Outpatient Services that Require Prior Authorization for one more service category. As we mentioned previously, we propose to incorporate additional codes into the existing Botulinum Toxin Injections service category that was established through the CY 2020 OPPS/ASC final rule with comment period.

2. Basis for Expanding Service Category

As part of our responsibility to protect the Medicare Trust Funds, we routinely analyze data associated with all aspects of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued

appropriateness of payment for services furnished in the hospital OPD setting.

In proposing the addition of these new services, we reviewed over 100 million OPD claims from 2017 through 2024. We determined that, on average, the number of OPD claims submitted for payment to the Medicare program decreased yearly by 1.1 percent. This reflects a decrease from approximately 114 million OPD claims submitted for payment in 2017 to approximately 104 million claims submitted for payment in 2024, with claim counts rounded for reporting purposes. The 1.1 percent decrease in overall OPD claims annually represents a decrease compared to the 0.6 percent increase identified in the CY 2023 OPPS/ASC proposed rule when we looked at the period from 2012 through 2021. Our analysis also showed that the Medicare allowed amount (the amount Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) for overall OPD claims increased from approximately $65.4 million in 2017 to approximately $101.1 million in 2024, representing an average annualized growth rate of 3.5 percent. Again, this is a decrease when compared to the 4.2 percent rate of growth identified in the CY 2023 OPPS/ASC proposed rule from 2012 through 2021. This analysis provides a benchmark regarding overall Medicare spending trends for OPD services during the same period.

In contrast to overall OPD utilization trends, utilization of all Botulinum Toxin Injection codes listed in Table 76 (2027 Proposed List of Additional Outpatient Department Services That Require Prior Authorization) has grown at a notably higher rate. This difference suggests that these services are increasing faster than overall OPD utilization, which warrants further review to ensure appropriate utilization. Our analysis of Integrated Data Repository (IDR) [180] data showed that claim volume for Botulinum Toxin Injection codes listed in Table 76 increased by 42.8 percent overall between 2017 and 2024,[181] based on a direct comparison of claims volume in 2017 and 2024, and there was a 4.6 percent average annualized growth rate increase during the same time period. Specifically, claims volume for the additional Botulinum Toxin Injection codes increased from approximately 43,500 claims submitted for payment in 2017 to approximately 62,103 claims submitted for payment in 2024. By comparison, the overall OPD claims volume decreased by 8.3 percent between 2017 and 2024,[182] based on a direct comparison of total OPD claims in 2017 and 2024, and by the 1.1 percent average annualized rate decrease in OPD claims submitted for payment during the same time period. We also recognize that additional FDA-approved indications for botulinum toxin products during this period may have contributed to some increase in utilization. However, the newly approved indications represent a limited number of additional clinical uses and are not expected to account for the full magnitude of the observed increase in utilization, suggesting that other factors may also be contributing. Accordingly, we do not believe that expanded indications alone fully explain the magnitude of the observed growth, which suggests that other factors may also be contributing to increased utilization. Specifically, overall OPD claims decreased from approximately 114 million claims in 2017 to approximately 104 million claims in 2024. The codes included in this proposal represent approximately $102 million in annual Medicare payments and constitute a subset of overall botulinum toxin utilization selected based on observed utilization volume, growth trends, and program integrity considerations.

When analyzing the data, we took the COVID–19 Public Health Emergency (PHE) into consideration. As a result of the PHE, health care use and spending dropped sharply due to cancellations of elective and non-emergency care to increase hospital capacity and social distancing measures to reduce the community spread of the coronavirus. Consequently, the claims data for CY 2020 showed a notable decrease in volume of services compared to the previous year. This decline in CY 2020 due to the PHE is reflected in the overall trend for the 2017 through 2024 period, including calculations of the 1.1 percent average annualized decrease in OPD claims submitted for payment over the 2017 through 2024 period discussed previously, which is based on year-over-year changes across all years in the period, including CY 2020. Although a decline in utilization was observed in CY 2020, claims volume for these services increased significantly in subsequent years and exceeded levels that would have been reasonably expected based on overall OPD utilization trends. Accordingly, we do not believe any claim decreases resulting from the PHE affect our conclusion that there were ''unnecessary increases in the volume of covered'' claims for these services. This determination is based on several considerations, including utilization growth for Botulinum Toxin Injection services substantially exceeding overall OPD utilization trends during the same period, despite overall OPD claims volume declining. In addition, the increased utilization persisted over multiple years rather than reflecting a temporary fluctuation. CMS also reviewed potential explanations for the increase in utilization, including changes in clinical need, coding changes, and other factors that could reasonably explain sustained growth in service volume, but did not identify sufficient evidence to account for the magnitude of the increase observed. CMS further considered broader program integrity concerns, including billing patterns and utilization trends that may indicate a risk of unnecessary utilization.

Our conclusion that increases in volume for Botulinum Toxin Injections are unnecessary is based not only on data specific to these services but also on a comparison of the rate of increase for these procedures to the overall trends for all OPD services. We believe that comparing the utilization rate for specific services to the overall Medicare OPD utilization trends is generally an appropriate method for identifying unnecessary increases in volume, particularly when there are no legitimate clinical or coding reasons for the changes. The Medicare allowed amount analysis discussed above provides additional information regarding broader Medicare spending trends during the same period. As we have stated in the previous OPPS/ASC final rules with comment period, we believe that prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in the volume of covered OPD Services without adding onerous new documentation requirements. Therefore,

[180] The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and durable medical equipment claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.*

[181] Using the formula (2024 claims − 2017 claims) ÷ 2017 claims, this results in a 42.8 percent increase. This calculation is separate from the 4.6 percent compound annual growth rate, which reflects the annualized rate of growth during the same period.

[182] Using the formula (2024 claims − 2017 claims) ÷ 2017 claims, this results in an 8.3 percent decrease. This calculation is separate from the 1.1 percent average annualized decrease, which reflects the average year-over-year change during the same period.

we believe prior authorization for these additional codes will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. This will also serve as a tool within CMS' broad program integrity strategy to address potential fraud, waste, and abuse. We request comments on the addition of these new services, specifically on the potential for unintended clinical consequences that may result from this addition.[183] [184] [185] [186]

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TABLE 76: 2027 PROPOSED LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning service dates on or after July 1, 2027	
Code	(2) Botulinum Toxin Injections
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed.
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64644	Chemodenervation of one extremity; 5 or more muscles
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

[183] CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

[184] CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

[185] CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule with comment period.

[186] CPT codes 64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)) and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)) will be removed on August 16, 2024.

TABLE 77: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(1) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair[181]
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(2) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(3) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(4) Rhinoplasty, and related services[182]
20912	Cartilage graft; nasal septum

Beginning for service dates on or after July 1, 2020	
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(5) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(6) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace

Beginning for service dates on or after July 1, 2020	
Code	(7) Implanted Spinal Neurostimulators [183]
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Beginning for service dates on or after July 1, 2023	
Code	(8) Facet Joint Interventions[184]
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

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XX. Codification of Section 6225 of the Consolidated Appropriations Act, 2026 for the Requirements for Provider-Based Status (§§ 413.65 and 419.23)

A. Background

Section 1861(u) of the Act lists the types of facilities that are regarded as providers of services but does not use or define the term ''provider-based''. Since the beginning of the Medicare program, however, 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 treatment, compared to being treated as a freestanding facility, provider-based facilities might experience a number of advantages, including most notably, increased payments from Medicare. Therefore, we have maintained that having clear criteria for treating a facility as provider-based, as opposed to operating as a freestanding facility, is important because failure to properly distinguish between the two risks inaccurate program payments, which can result in provider overpayments and increased beneficiary coinsurance liability, with no commensurate benefit to the Medicare program or its beneficiaries. Section 413.65 specifies the criteria for treating a facility as provider-based and the requirements for a CMS determination of provider-based status, including an attestation by the provider that the facility meets the provider-based criteria. Provider compliance with provider-based rules is mandatory, but since the passage of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554, App'x F), a provider has needed to submit an attestation only if it wishes to obtain a CMS determination of provider-based status.

B. Requirements at Section 6225 of the Consolidated Appropriations Act, 2026

Section 6225 of the Consolidated Appropriations Act, 2026 (CAA, 2026), Public Law 119–75, enacted on February 3, 2026, amends section 1833(t) of the Act by adding new paragraph (23). In brief, section 6225 of the CAA, 2026 will prohibit Medicare payments under the OPPS beginning January 1, 2028, unless off-campus outpatient departments of a provider bill using a separate National Provider Identifier (NPI) and the main provider has submitted an attestation that the departments meet the provisions at § 413.65. As noted previously, although provider compliance with provider-based rules is mandatory, payment had not been conditioned on verification of such compliance.

Section 1833(t)(23)(A) of the Act, as added by section 6225 of the CAA, 2026, specifies that no payment may be made under that subsection (or under an applicable payment system pursuant to paragraph (21) of section 1833(t) of the Act) for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider unless that department has obtained, and the items and services are billed under, an NPI that is separate from the NPI of the main provider; the main provider has submitted to the Secretary, during the 2-year period

ending on the date such items and services are furnished, an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65 (or a successor regulation); and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. The initial attestation may include an attestation submitted in accordance with existing § 413.65(b)(3) until the Secretary establishes the new attestation submission process, which is discussed further below.

New section 1833(t)(23)(B)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish a process for each provider with an off-campus outpatient department to submit an initial and subsequent attestation, for the review of each such attestation and for the determination, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether each off-campus outpatient department is compliant with the requirements described in subparagraph (A). In addition, new section 1833(t)(23)(C) of the Act defines an ''off-campus outpatient department of a provider'' for purposes of paragraph (23) as a department of a provider (as defined in § 413.65) that is not located on the campus (also defined in § 413.65) of the main provider or is not within the distance described in such definition of campus from a remote location of a hospital (also defined in § 413.65).

C. Proposed Modifications To Implement the Provisions of Section 6225 of the CAA, 2026

1. Proposed Modification to the Hospital OPPS Regulations

As discussed previously, section 1833(t)(23)(A) of the Act, as added by section 6225, specifies that no payment may be made under the OPPS for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider unless that department has obtained, and the items and services are billed under, an NPI that is separate from the NPI of the main provider; the main provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are furnished, an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65; and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. We are proposing to add new section § 419.23 to codify this requirement. (We note the proposed changes to the provider-based regulations at § 413.65 to implement the attestation requirements are discussed in the next section. We also note, as discussed in greater detail in the next section, we propose that prior to submitting an attestation, providers must obtain an NPI for each provider-based department.)

2. Proposed Modifications to the Provider-Based Regulations at § 413.65

In this proposed rule, we propose changes to the provider-based regulations at § 413.65 to implement the new requirements in section 6225 of the CAA, 2026. First, we propose the addition of a new entry in the list of definitions in § 413.65(a)(2) for an ''Off-campus outpatient department of a provider''. CMS currently defines a ''department of a provider'' as a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider. The definition of a department of a provider does not include rural health clinics (RHCs) or, except as specified in § 413.65(n), Federally Qualified Health Centers (FQHCs). In accordance with the statutory definition provided in section 1833(t)(23)(C) of the Act, we propose to add a new definition to paragraph (a)(2) describing an off-campus outpatient department of a provider as a department of a provider that is not located on the campus of the main provider or within 250 yards of a remote location of a hospital. Under this proposed definition, facilities or organizations that are not located on the campus of the main provider would be considered off-campus for provider-based purposes. This would include remote locations of a hospital, which are defined in § 413.65 as facilities that provide inpatient services in a location off the campus of a main provider. Remote locations are often referred to as secondary or subordinate ''multi-campus'' locations of a hospital, and in most cases operate in a substantially similar manner as the main provider. Section 6225 of the CAA, 2026, adding section 1833(t)(23)(C) to the Act, defines an ''off-campus outpatient department of a provider'' as neither being on the campus of the main provider, nor within the distance specified in the definition of campus of a remote location of a hospital.

Section 413.65(e) includes additional requirements applicable to off-campus facilities or organizations. These requirements apply to all off-campus outpatient facilities, including those that are in close proximity to (and often within the same building as) inpatient remote locations. The implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74) in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729), however, excepted outpatient departments located within 250 yards of a remote location from payment policy implications for off-campus departments. Given the definition of an ''off-campus outpatient department of a provider'' in section 603 of the Bipartisan Budget Act of 2015 and section 6225 of the CAA, 2026 separates outpatient departments located outside the regulatorily-specified distance of a remote location of a hospital and provider off-campus outpatient departments, we believe that it would be appropriate to distinguish off-campus requirements from those for hospital outpatient departments that are within 250 yards of a remote location of the main provider. Therefore, we propose to revise § 413.65(e) to specifically exclude outpatient departments located within 250 yards of a remote location of a hospital, and to revise § 413.65(b)(3)(ii), (g)(1)(i), and (h) to append ''or within 250 yards of a remote location of a hospital'' to the references of being on the campus of the main provider. We believe these proposed conforming changes will better clarify which facilities are affected by the new legislation and will better align the current provider-based rules with statutory provisions regarding the distinction between on- and off-campus locations and services. In addition, we propose to make a technical change to § 413.65(g)(1)(i) and (ii) to revise ''treated by Medicare'' to ''treated by CMS'' consistent with the other proposals discussed in this section.

We propose to add a reference to the new mandatory attestation requirements required by section 6225 of the CAA, 2026 and propose a maximum 5-year timeframe for any subsequent attestation(s). Specifically, we propose to add § 413.65(b)(6) to state that, as of January 1, 2028, a main provider must submit an initial attestation of provider-based status for each of its off-campus outpatient departments within the 2-year period prior to furnishing services, and subsequent attestation(s) within a period not to exceed 5 years thereafter.

We anticipate addressing the subsequent attestation requirement in the 2028 rulemaking cycle; nonetheless, we welcome comments on the subsequent attestation at this time. For all off-campus outpatient departments providing services on or before January 1, 2028, we propose initial attestations must be submitted between January 1, 2026 and December 31, 2027, and off-campus outpatient departments that begin providing services after January 1, 2028, must submit an attestation within the 2 years prior to when the billed services are delivered. Subsequent attestation(s) would be submitted at an interval to be specified by CMS and not to exceed 5 years thereafter. In addition, providers who submit initial attestations within the 2-year period prior to January 1, 2028, would meet the attestation requirements of section 6225 of the CAA, 2026, even if they have not received a provider-based status determination from CMS by January 1, 2028. We also seek comments on an initial mandatory attestation for provider departments that received a determination of provider-based status prior to January 1, 2026, and remain in compliance with all applicable provisions of § 413.65. For these departments, we are considering having the authorized official attest with a letter to CMS with evidence of CMS determination attached affirming its continued compliance with § 413.65. Indian Health Service and Tribal facilities described in § 413.65(m) and certain FQHCs and ''look alikes'' described in § 413.65(n) are considered to be in compliance with provider-based requirements, and would not be subject to review of provider-based status. We, therefore, propose to exclude these facilities from the proposed attestation requirements. Other parts of § 413.65 not specifically addressed are outside the scope of this rulemaking.

To implement section 6225 of the CAA, 2026, we propose to establish a standardized attestation form for provider-based determinations, which would replace the current Medicare Administrative Contractor (MAC)-specific templates and ensure consistency across MACs. Through this standardization, CMS proposes that main providers would submit the attestation through a centralized electronic system, which we believe would result in a reduction in administrative burden for providers and a more efficient review process for MACs and CMS. Further, we anticipate that standardization and centralized submission processes may reduce unnecessary duplicative documentation burden while continuing to support appropriate compliance review and program integrity oversight. Until the standardized form and centralized electronic system are finalized, providers may continue to submit attestations in accordance with existing § 413.65(b)(3)(ii) in satisfaction of section 6225 of the CAA, 2026 to their servicing MAC.

To ensure providers have clarity on how to satisfy the mandatory attestation requirement under section 6225 of the CAA, 2026, we propose to require that providers submit attestations using the referenced CMS-standardized attestation form. The attestation would be a list of identifying information of the main provider and provider-based department such as name, address, and NPI that includes a list of the requirements at § 413.65(d)(e), (g), and (h) with a certifying statement affirming compliance to be signed by an authorized official of the main provider. A draft is located at the following link for comment: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1850-p.* Under the current attestation process, providers submit their attestations and supporting documentation to their MAC, which performs a preliminary review and forwards its recommendation to CMS for the initial determination. We propose to modify this process so that CMS' contractors, including MACs, conduct standardized review and validation activities in support of initial determination regarding compliance with § 413.65, rather than requiring separate CMS review of each attestation recommendation. To reflect this proposal, we propose to revise § 413.65(b)(3)(iii) to specify that CMS ''or its agents'' will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness and consistency with information in the possession of CMS ''or its agents'' at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based. We also propose that the determinations issued through this process would constitute CMS initial determinations for purposes of § 498.3(b)(2). In conducting review and validation activities, CMS and its contractors, including MACs, would employ standardized review, validation, and risk-based screening processes to assess attestations for completeness, consistency with the provider's enrollment records, and compliance with the applicable requirements of § 413.65. These processes may include automated validation activities, data analysis, targeted documentation review, and contractor review procedures designed to support consistent national implementation and program integrity oversight. We propose to establish, through operational guidance, specific review criteria, validation protocols, and documentation standards that CMS and its contractors, including MACs, must apply in conducting review and validation activities and supporting initial determinations, in order to promote consistent assessment of provider-based requirements across all CMS contactors including MAC jurisdictions. CMS will conduct ongoing quality review and oversight of attestation determinations and related review activities. (For additional discussion of our proposed documentation requirements for provider-based attestations and proposed verification and oversight activities, refer to sections XX.D, and XX.E, respectively, of this preamble.)

We also propose an additional modification to § 413.65(b)(3)(ii) to revise the timing and modernize the manner in which supporting documentation is submitted for off-campus provider-based facilities and organizations. CMS and its contractors, including MACs, proposed to employ standardized review and validation processes, including automated validation activities, data analysis, risk-based screening methodologies, targeted documented review, and other program integrity activities, to evaluate attestations and identify submissions requiring additional review of compliance verification. Providers would continue to be required to maintain documentation demonstrating compliance with applicable provider-based requirements and to furnish such information to CMS or its contractors, including MACs, upon request as part of review, validation, audit, or oversight activities. We believe these proposals will afford providers greater flexibility in meeting the statutory deadlines imposed by section 6225 of the CAA, 2026, while continuing to allow CMS oversight and access to information necessary to evaluate compliance and make a determination. We also propose a modification to § 413.65(k) to remove references to what constitutes a 'complete' attestation, with supporting documentation and additional information to be requested from the provider, as necessary, after the standardized attestation form has been submitted.

We propose that main providers, prior to submitting an attestation, must obtain an NPI for each provider-based department and update Provider Enrollment, Chain, and Ownership System (PECOS). As discussed previously, to implement section 6225 of the CAA, 2026, CMS proposes to establish a standardized attestation form for provider-based determinations that would replace the current MAC-specific templates; the attestation would then be submitted through a centralized electronic system. We believe this standardized approach would ensure consistency across MACs and would result in a reduction in administrative burden for providers and a more efficient review process for MACs and CMS. For providers that submit attestations for more than one off-campus outpatient department, CMS is considering streamlined supporting documentation requirements and seeks input on how best to minimize burden while ensuring robust oversight. Further, we anticipate a reduction in the documentation supporting the attestation. For instance, we anticipate leveraging system capabilities to reduce duplicative documentation submissions by allowing supporting documentation applicable to multiple locations to be submitted a single time, where appropriate.

The future standard attestation format would request identifying information for both the main provider and the provider-based entity, including applicable NPIs. Once all attestations are submitted, providers would indicate their submission is complete. CMS and its contractors, including MACs, may employ automated validation, screening, targeted review and risk-based methodologies to identify attestations requiring additional review, supporting documentation, or follow-up activities. We anticipate giving providers a reasonable period, generally not to exceed 60 days, to furnish requested supporting documentation.

If CMS or its contractor, including MACs, determine that an attestation demonstrates compliance with the provider-based requirements at § 413.65, we propose that an approval notice would be issued. CMS and its contractor, including MACs, propose to request supporting documentation at any stage of the review, validation, audit or oversight process to evaluate compliance with applicable provider-based requirements. If CMS or its contractor determines that an attestation fails to demonstrate compliance with the provider-based requirements, or if the provider fails to furnish all requested information or attest to all applicable requirements, we propose that a denial would be issued, including applicable appeal rights. Until the standardized form and centralized electronic system are finalized, we propose providers may continue to submit attestations in accordance with § 413.65(b)(3), in satisfaction of Section 6225. As noted previously, an off-campus outpatient department of a provider will also need to obtain an NPI before January 1, 2028, consistent with section 1833(t)(23)(A)(i) of the Act as added by Section 6225.

In addition, we propose to use program integrity mechanisms currently available to CMS, or that may become available in the future, whether through improved technology, contracting, data analysis or other means, to evaluate compliance with provider-based requirements and identify attestations requiring additional review or oversight activities. In § 413.65(k), we propose to specify that these activities may include site visits, remote audits, investigations, or require submission of additional documentation as may be necessary to make a determination of compliance with the provider-based requirement, and the use of current or future Medicare program integrity contractors. We believe this proposal would continue to address CMS' longstanding concerns, regarding potential increased costs to the Medicare program and its beneficiaries by ensuring compliance with provider-based regulations. For additional discussion of our proposed documentation requirements for provider-based attestations, refer to section XX.D of this preamble. For additional discussion of the proposed CMS verification and oversight activities, refer to section XX.E of this preamble.

D. Documentation Requirements for Provider-Based Attestations

To support meaningful CMS oversight of provider compliance with the provider-based requirements of § 413.65, and consistent with the mandatory attestation requirement established by section 6225 of the CAA, 2026, we propose that attestations submitted through the proposed standardized attestation process include, or be supported by, documentation sufficient to demonstrate compliance with the applicable provisions of § 413.65(d), (e), (g), and (h). We describe in this section the categories of documentation that providers may be required to submit or retain in connection with their attestations. As discussed further, CMS anticipates that not all documentation described herein would be required at the time of initial attestation submission; rather, CMS and its contractors, including MACs, will employ risk-based screening and targeted documentation review processes to identify those attestations for which additional documentation is warranted. The rationale behind using targeted documentation review is that any main provider typically manages its departments in a consistent manner. By drawing a sample from each main provider's universe of provider-based departments, we would be able to gain a reliable understanding of their universe. This approach would not only ensure adequate representation across all providers, regardless of their volume—it would also provide meaningful insight into whether compliance standards are being upheld across all departments. We invite public comment on the appropriate scope of documentation requirements, including whether any of the categories described should be modified, consolidated, or eliminated in order to reduce provider burden while preserving CMS' ability to evaluate compliance and protect the Medicare program. Specifically, we propose the following documentation framework:

- *Attestation Form Completeness and Authorization:*

++ We propose that providers must submit a completed attestation using the CMS-standardized attestation form, signed and dated by an authorized official of the main provider as identified in PECOS. The attestation would be required to identify both the main provider and each off-campus outpatient department of the provider for which provider-based status is sought, including the applicable NPIs, provider numbers, addresses, and the date on which provider-based conditions were met or the date the department was acquired, as applicable. Where a provider designates a consultant or outside representative as the primary contact for the attestation, we propose the provider must authorize the representative in writing.

- *Location:*

++ We anticipate the attestation system would have the ability to measure the distance requirement. However, if the distance is not systematically verified or exceeds 35-miles, we propose providers would be required to submit supporting documentation in support of § 413.65(e)(3).

- *Licensure:*

++ We propose providers must be prepared to demonstrate that the off-campus outpatient department is operated under the same licensure as

the main provider, consistent with § 413.65(d)(1), or to provide documentation that the applicable State does not require a separate license for the department.

• *Clinical Services Integration:*

++ We propose providers must be prepared to demonstrate that the off-campus outpatient department meets the clinical integration requirements of § 413.65(d)(2), including that professional staff at the department hold privileges at the main provider; that appropriate monitoring and oversight of the department by the main provider is in place; that inpatient and outpatient services of the department and the main provider are integrated; and that patients treated at the department who require further care have full access to all services of the main provider.

• *Financial Integration:*

++ We propose providers must be prepared to demonstrate that the revenues and expenses of the off-campus outpatient department are integrated with those of the main provider, consistent with § 413.65(d)(3), such that the department does not maintain a separate general ledger or trial balance independent of the main provider.

• *Public Awareness:*

++ We propose that providers must be prepared to demonstrate that the off-campus outpatient department is clearly identified to the public as part of the main provider, consistent with § 413.65(d)(4), and that patients entering the department are aware they are receiving services from the main provider.

• *Obligations of Hospital Outpatient Departments:*

++ For off-campus outpatient departments that are departments of hospitals, we propose that providers must be prepared to demonstrate compliance with the applicable obligations of hospital outpatient departments under § 413.65(g), including compliance with Emergency Medical Treatment and Labor Act (EMTALA) requirements, antidumping rules, site-of-service billing requirements, and the requirement to provide written notice to Medicare beneficiaries of their potential financial liability prior to the delivery of services at an off-campus location.

• *Ownership, Control, Administration, and Supervision (Off-Campus Departments):*

++ We propose providers must be prepared to demonstrate that the department operates under the ownership and control of the main provider consistent with § 413.65(e)(1), including that the department is 100 percent owned by the main provider and that the main provider retains final approval over administrative decisions, personnel policies, and medical staff appointments. We also propose providers must also be prepared to demonstrate that the administrative functions of the department are integrated with those of the main provider consistent with § 413.65(e)(2), including through submission of an organizational chart reflecting the reporting relationship between the department and the main provider.

E. CMS Verification and Oversight Activities

Section 1833(t)(23)(B)(i) of the Act directs the Secretary to establish a process for determining, through site visits, remote audits, or other means as determined appropriate by the Secretary, whether each off-campus outpatient department of a provider is compliant with the applicable requirements. Consistent with this statutory direction, we propose that CMS and its contractors, including MACs, employ a layered, risk-based approach to verification and oversight that is designed to promote efficient processing of the significantly increased volume of attestations expected under the mandatory attestation requirement while preserving meaningful CMS oversight of provider compliance with § 413.65.

At the initial review stage, CMS and its contractors, including MACs, would conduct automated validation and screening of all submitted attestations to verify completeness, consistency with PECOS enrollment records, and the presence of required attestation elements. Attestations that pass automated validation would be processed for initial determination. Attestations that present indicators of incompleteness, inconsistency, or elevated compliance risk would be flagged for targeted documentation review, during which CMS or its contractors may request that the provider furnish supporting documentation from any or all of the categories described.

At the extended review stage, CMS and its contractors, including program integrity contractors, would employ risk-based methodologies to select a subset of attestations for more extensive compliance review. Such methodologies may include remote audits of provider records and documentation, site visits conducted by CMS or contractors to verify that the attested department meets the physical, financial, clinical, and administrative integration requirements of § 413.65, or investigations of potential non-compliance identified through data analysis, referral, or other sources. The criteria and methodologies CMS would use to select attestations for extended review would be established through operational guidance and would be designed to focus oversight resources on providers and departments that present the highest risk of non-compliance with the provider-based requirements. We propose that failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of payments as described in § 413.65 (k).

We invite public comment on the appropriate scope and sequencing of documentation requirements, including whether the categories described should be further prioritized, consolidated, or phased in over time to facilitate provider compliance with the January 1, 2028 statutory deadline.

We solicit public comment on the proposed policies and processes described in this section. Specifically, we seek feedback from stakeholders regarding feasibility, operational impact, implementation considerations, potential burden, and any unintended consequences associated with these proposals. We encourage commenters to provide detailed rationale, data, examples, or alternative approaches that may assist CMS in evaluating and refining the final policy.

XXI. Payment for Direct and Indirect Graduate Medical Education (GME) Costs—Notice of Closure of Teaching Hospital 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. These changes instruct the Secretary to establish a process to increase the full-time equivalent (FTE) resident caps at other hospitals based upon the FTE resident caps at teaching hospitals that closed on or after March 23, 2008. In the CY 2011 OPPS/ASC 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 graduate medical education (GME) and indirect medical education (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 to teaching hospitals that closed between March 23, 2008, and August 3, 2010, and to teaching hospitals that close after August 3, 2010 (75 FR 72215).

B. Notice of Closure of Louis A. Weiss Memorial Hospital Located in Chicago, Illinois and the Application Process—Round 29

CMS learned of the closure of Louis A. Weiss Memorial Hospital, located in Chicago, Illinois (CCN 140082). Accordingly, we are providing notice of the closure of this teaching hospital and initiating another round of the application and selection process to redistribute the closed hospital's FTE resident caps. This round will be the 29th round (''Round 29'') of the application and selection process. Table 78 contains the identifying information for the closed teaching hospital and its IME and direct GME FTE resident caps, which are part of the Round 29 application process under section 5506 of the Affordable Care Act.

TABLE 78: LOUIS A. WEISS MEMORIAL HOSPITAL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including+/- MMA Sec. 422[1], +/- ACA Section 5503[2], and + ACA Section 5506[3] adjustments)	Direct GME FTE Resident Cap (including+/- MMA Sec. 422, +/- ACA Section 5503, and + ACA Section 5506 adjustments)
140082	Louis A. Weiss Memorial Hospital	Chicago, IL	16984	August 9, 2025	81.69 - 1.41 sec. 422 reduction – 4.46 sec. 5503 reduction + 10.00 sec. 5506 increase = 85.82[4]	60.66 – 0.28 sec. 422 reduction – 3.59 sec. 5503 reduction + 10.00 sec. 5506 increase = 66.79[5]

1 Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
2 Section 5503 of the Affordable Care Act of 2010, Pub. L. 111–148 and Pub. L. 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.
3 Section 5506 of the Affordable Care Act of 2010, Pub. L. 111–148 and Pub. L. 111–152, redistributes IME and direct GME residency slots from teaching hospitals that close on or after March 23, 2008
4 Louis A. Weiss Memorial Hospital's 1996 IME FTE resident cap is 81.69. Under section 422 of the MMA, the hospital received a reduction of 1.41 to its IME FTE resident cap. under section 5503 of the ACA, the hospital received a reduction of 4.46 to its IME FTE resident cap, and under section 5506 of the ACA, the hospital received an increase of 10.00 to its IME FTE resident cap: 81.69 – 1.41 – 4.46 – 10.00 = 85.82.
5 Louis A Weiss Memorial Hospital's 1996 DGME FTE resident cap is 60.66. Under section 422 of the MMA, the hospital received a reduction of 0.28 to its DGME FTE resident cap. under section 5503 of the ACA, the hospital received a reduction of 3.59 to its DGME FTE resident cap. and under section 5506 of the ACA, the hospital received an increase of 10.00 to its DGME FTE resident cap: 60.66 – 0.28 – 3.59 +10.00 = 66.79.

C. 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). Hospitals that wish to apply for and receive slots from the previously noted hospital's FTE resident caps must submit Round 29 applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™) between July 13, 2026, and October 13, 2026. The section 5506 application can be accessed at *https://mearis.cms.gov/public/home.*

CMS will only accept Round 29 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:

- 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 through MEARIS 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 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.

XXII. Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines

In the ''Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals'' advance notice of proposed

rulemaking (91 FR 3851),[187] we sought public comment on potential options we could consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety, and to reflect the additional resource costs incurred when procuring these domestically manufactured items. We sought input on a possible new ''Secure American Medical Supplies'' friendly designation that could be earned by hospitals that demonstrate their commitment to domestic procurement. In addition, we sought input on potential ways such a designation could facilitate the creation of new, streamlined payment policies to support hospitals in their efforts. We also sought input on a potential new structural quality measure as part of the Hospital Inpatient Quality Reporting (IQR) Program that could promote hospital commitments to invest in domestic procurement to secure our nation's health and safety.

We are now seeking further public input on this issue after reviewing the comments on the ANPRM. Specifically, we are soliciting public comment on potential policy approaches for a payment adjustment, a methodology to calculate the price differential between domestic and non-domestic PPE and essential medicines, information sources of those price differentials, a definition of domestic essential medicine and PPE, and a process for verifying that a given essential medicine or PPE is ''domestic.''

A. Overview

We continue to believe that hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for domestically manufactured goods, which is foundational to safeguarding timely access and continuity of care for patients. Because hospitals are the primary purchasers and users of essential medicines and medical PPE, we believe a voluntary payment adjustment that reflects the additional marginal costs that hospitals face in procuring these products may help to sustain their domestic production and availability and thereby help to safeguard personnel and beneficiary safety over the long term.

We currently have a voluntary payment policy under the IPPS and OPPS for the additional resource costs that hospitals face in procuring domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 filtering facepiece respirators (FFRs). Building on public input from the ANPRM, we are considering expanding the existing IPPS payment policy to include other forms of domestic PPE and certain essential medicines.

1. Expanded Scope of PPE and Domestic Definition

For PPE, as discussed in section XXII.C., we are considering expanding the policy to include all domestic NIOSH-approved filtering face piece respirators that demonstrate compliance with the American Society for Testing and Materials (ASTM) Respirator Fit Capability Standard; domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards; and domestic gowns in compliance with FDA requirements and conforming to Association for the Advancement of Medical Instrumentation (AAMI) standards. We are considering defining the term ''domestic'' using the contract terms listed in the Make PPE In America Act, (section 70953 of Pub. L. 117–58), which identifies American-made PPE as domestically-made from domestic materials and components that are ''grown, reprocessed, reused, or produced in the United States''. Given the lack of available domestic nitrile butadiene rubber (NBR),[188] we are considering an exception for nitrile gloves which are made in the U.S. with foreign rubber. Future rulemaking may revisit this potential exception in the event that domestically produced NBR becomes available.

2. Potentially Eligible Essential Medicines and Domestic Definition

For essential medicines, as discussed in section XXII.D., we are seeking comment on including in an expanded policy certain FDA-approved medicines which have existing U.S. finished dosage form (FDF) production and do not contain API from countries listed on the ''foreign adversaries'' list at 15 CFR 791.4.[189] As discussed further in sections XXII.C. and XXII.D., in developing this potential subset of eligible essential medicines, we prioritized non-substitutable sterile injectables and generic antibiotics as per the prioritization framework developed by ASPR and Federal supply chain security offices, including within HHS and the Department of War (DOW). We are seeking comment as to whether an essential medicine should be defined as domestic if the country of origin is the United States (U.S.), where country of origin is defined through incorporation by reference as the country in which ''substantial transformation'' of the final dosage form occurs via 19 CFR 134.1(b).

3. Domestic and Non-Domestic Cost Differential

As also discussed in sections XXII.C and XXII.D, we are considering whether the methodology for determining the amount of the payment adjustment should be based on the use of standardized cost differentials for eligible domestic PPE and essential medicines, which would be updated on an annual basis. We seek comment on the potential base cost differentials for eligible categories of PPE in section XXII.C. and the potential base cost differentials for eligible essential medicines in section XXII.D.

4. Manufacturer Attestation of Domestic Origin

Additionally, as discussed in section XXII.E., we are considering whether under a potential policy a manufacturer should voluntarily be able to provide an attestation to HHS that its product meets the applicable domestic definition. To make it easier for hospitals to identify domestic products, HHS would compile these attestations annually and create a public file of eligible products by National Drug Code (NDC) or Unique Device Identifier (UDI), as applicable, based on the information provided by the manufacturers. Only products in this file would be eligible for separate payment.

5. Potential Payment Adjustment Approaches

We are also seeking feedback on different potential approaches under the IPPS to separately pay for the additional resource costs that hospitals face when purchasing eligible domestic PPE and essential medicines. These approaches are discussed in section XXII.F.

6. Annual Spending Threshold

As discussed in section XXII.G., under any approach that may be considered, we believe it also may be prudent to consider establishing an appropriate maximum annual amount of aggregate separate payment under this policy and to prospectively allocate shares of that amount to individual hospitals before the start of the fiscal year. Under this approach, if the actual separate payment to a hospital for the fiscal year exceeds its allocated

[187] Hereinafter referred to as ''the ANPRM''.

[188] *https://www.madeinamerica.gov/waivers/nonavailability/6994cfdf16e70851109b4247.*

[189] *https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-E/part-791/subpart-A/section-791.4.*

maximum amount, the excess amount would be reconciled at cost report settlement, as that excess amount would be considered still bundled into the MS–DRG payment and not separately payable.

B. Background and Summary of Prior Rulemaking

As discussed in the ANPRM, sufficient domestic availability of PPE and essential medicines in the health care sector is a critical component of emergency public health preparedness. In the spring of 2020, supply chains for PPE faced severe disruptions due to lockdowns that limited production and unprecedented demand spikes across multiple industries. Supplies of N95® FFRs, nitrile gloves, and isolation gowns were examples of PPE that experienced significant supply chain disruptions. So-called ''just-in-time'' supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough PPE to protect health care workers. Similarly, shortages for critical medical products have persisted, with a recent report authored by the Senate Committee on Homeland Security and Government Affairs noting that the average drug shortage lasts about 1.5 years.[190] For pharmaceuticals, hospitals reported more than 40 drug shortages at the time they were surveyed—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.[191] Historically, most shortages occur after quality-related breakdowns in manufacturing processes, as generic drug manufacturers face intense price competition, uncertain revenue streams, and high investment requirements to maintain mature manufacturing quality systems.[192] Shortages of both essential medicines and reliable PPE jeopardize patient safety and health care quality, and it is therefore critical to ensure that quality PPE and essential medicines are available to health care personnel and patients when needed. The COVID–19 pandemic illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. Sustaining domestic production of these important medical supplies is therefore critical in ensuring patients and health care personnel have the critical medical supplies they need.

In recent years we have solicited comment on, and based on feedback from interested parties, implemented payment adjustments to Medicare participating hospitals to reflect the additional costs of procuring domestically made surgical N95 FFRs and creating and maintaining buffer stocks of certain essential medicines.[193] In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72037), we implemented payment adjustments under the IPPS and OPPS to support a resilient and reliable domestic supply of NIOSH-approved® surgical N95 respirators. This payment adjustment is based on the IPPS and OPPS shares of the difference in cost between domestic and non-domestic NIOSH-approved surgical N95 FFRs and is available where those costs are separately tracked, reported, and appropriately claimed by the hospital on its cost report submitted to Medicare. As discussed in the CY 2023 OPPS/ASC final rule with comment period, the payment adjustment was intended to account for the marginal costs that hospitals face in procuring domestically made NIOSH-approved and FDA-certified surgical N95 FFRs. These marginal costs are due to higher per-unit acquisition prices that stem from higher costs of inputs and labor in the U.S. as compared to international suppliers, which make many N95 and other FFRs, as well as a demonstrated record of more consistent high-quality for domestically made products. Usage of the payment adjustments has been limited, and HHS conducted outreach to interested parties to better understand barriers to awareness and uptake and seek feedback on potential modifications that could increase effectiveness. For FY 2024, fewer than 100 hospitals reported the information necessary to determine the payment adjustment on their cost reports. This low adoption rate may have been partially attributable to administrative reporting burden concerns raised by interested parties.

As noted in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72039), we received many comments urging us to expand this policy to cover other forms of PPE and critical medical supplies. A few commenters stated that other forms of PPE are susceptible to shortages similar to surgical N95 FFRs, and therefore investing in domestic production for these products was also important for future emergency preparedness. We stated that we would consider these comments, and other modifications to the payment adjustment, for future rulemaking as we gained more experience with our policy.

In addition to PPE, essential medicines are another critical component of preparedness. In the FY 2025 IPPS/Long-Term Care Hospital (LTCH) PPS final rule (89 FR 68986, 69387 through 69400), we finalized a separate payment under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of one or more essential medicines. Under this policy, essential medicines are defined as the medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (formally known as the Office of the Assistant Secretary for Strategic Preparedness and Response) and published in May 2022, and any subsequent revisions to that list of medicines.[194] The President's Executive Order 14336 further required that the ASPR provide the Assistant to the President and Homeland Security Advisor (APHSA), the Assistant to the President for Economic Policy (APEP), and the Office of Management and Budget (OMB) with an update to this list.[195]

We solicited feedback and comments in the CY 2025 OPPS/ASC proposed rule (89 FR 59186, 59396 through 59399) on potential modifications to the surgical N95 FFR policy to increase hospital uptake, reduce reporting burden, and achieve the policy goal to maintain a baseline domestic production capacity of PPE to ensure

[190] Senate Committee on Homeland Security & Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages, March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[191] Vizient, Beyond the shortage: The hidden cost of drug supply chain disruptions, June 2025: *https://www.vizientinc.com/newsroom/news-releases/2025/new-vizient-survey-finds-drug-shortages-cost-hospitals-nearly-900m-annually-in-labor-expenses.*

[192] U.S Department of Health and Human Services: Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States, April 2024: *https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.*

[193] Hereafter referred to as ''the N95 policy'' and ''the essential medicines policy,'' respectively.

[194] The list is available at *https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf* and there have been no public revisions to the list yet.

[195] *https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/.*

that quality PPE is readily available to health care personnel when needed. As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912, 94290 through 94295), commenters were supportive of a variety of modifications to the established policy, including modifications to the payment adjustment methodology calculation that would provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 FFRs, stating that such a modification would minimize reporting burden for hospitals and ensure payments to hospitals are equitable. We note that some commenters differed in their view as to how the cost differential should be calculated. Commenters also stated that expanding the payment adjustment to more products would increase uptake of the payment adjustment by hospitals, strengthen the existing U.S. manufacturing base, incentivize other manufacturers to prioritize domestic production, and protect access to high-quality products. Commenters requested that CMS work with the Congress to give CMS authority to offset all the marginal costs incurred by the hospital in procuring domestically manufactured surgical N95 FFRs rather than just the Medicare share of these costs. Some commenters also indicated that hospitals have had difficulty ascertaining which products meet the definition of domestic under the surgical N95 FFR policy and were supportive of making publicly available a list of products eligible under the surgical N95 FFR policy.

As discussed in the CY 2025 OPPS/ASC final rule with comment period, several commenters urged CMS to expand the payment adjustment to include other PPE types and medical devices (89 FR 94295). Examples from commenters included isolation gowns, hair nets, beard covers, bouffant caps, shoe covers, face shields, ASTM level II and III surgical masks, powered air purifying respirators, elastomeric respirators, syringes, needles, catheters, and wound care dressings. Commenters indicated that many of these products are currently being purchased from non-domestic manufacturers and have been prone to shortages and quality issues. For example, a commenter cited safety concerns regarding the quality of imported syringes and needles which they stated have had issues ranging from leaks to breakages that compromise patient safety.

In the ANPRM, we solicited comment on potential options we might consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety and to reflect the additional resource costs incurred when procuring these domestically manufactured items. These potential options included the creation of a ''Secure American Medical Supplies'' friendly designation that could be earned by hospitals with a demonstrated commitment to procuring domestic PPE and domestic essential medicines, a potential separate Medicare payment to ''Secure American Medical Supplies'' friendly hospitals, and a structural measure that would require hospitals to attest to meeting the domestic procurement designation minimum percentages for PPE and essential medicines as part of the Hospital IQR Program.

Commenters generally continued to support CMS' efforts to foster a more resilient domestic supply chain for critical medical supplies and favored voluntary, non-budget-neutral payment approaches over quality measures or payments tied to hospital designations. Commenters raised concerns about administrative burden, and many hospitals highlighted challenges in identifying qualifying domestic products and tracking their use, as well as other costs associated with domestic purchasing. Commenters also urged creating a public list of eligible domestic products, standardizing the domestic cost differentials, and expanding the eligible product categories.

Several commenters emphasized that long-term, committed contracting arrangements (for example, 2- to 3-year or longer arrangements) between purchasers and manufacturers of domestic medical supplies would be necessary to increase the domestic manufacturing base. Some commenters stated that CMS would need to pay beyond the IPPS and OPPS shares of the additional costs in a non-budget neutral manner to shift purchasing, with several commenters suggesting that CMS work with Congress to achieve this objective. Some commenters supported the establishment of a resiliency [196] measure to supplement or replace the quality measure discussed in the ANPRM. Several of these commenters advocated for any potential separate payment to be tied to demonstrated efforts on the part of hospitals and manufacturers to implement resiliency processes into their procurement practices.

C. Potential Eligible Domestic PPE Products and Cost Differentials

As described previously in section XXII.B., under the IPPS we currently make a payment adjustment for the additional resource costs that hospitals face in procuring domestic NIOSH-approved® surgical N95® respirators.[197] After consideration of the comments received on the ANPRM, to further support a level of supply resilience that is critical to protect the health and safety of personnel and patients, we are considering expanding the PPE products eligible for the separate IPPS payment adjustment to include all domestic NIOSH-approved FFRs that demonstrate compliance with the ASTM Respirator Fit Capability Standard, domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards, and domestic gowns in compliance with FDA requirements and conforming to AAMI standards. We are not considering including other PPE products such as face shields, protective eyewear, surgical masks, and head and foot coverings at this time.

Given that the unique device identifier (UDI) codes for PPE, as applicable, may refer to packages of multiple items, our unit of analysis is a single item (that is, one glove). As previously noted, we are considering whether the methodology for determining the amount of the payment adjustment under any such expanded policy should be based on the use of standardized cost differentials for eligible categories of domestic PPE.

Potential eligible PPE items, per item differentials, and qualifying criteria under consideration are listed in Table 79. These potential PPE cost differentials were derived from public comments, prior discussions with manufacturers, and Federal procurement data. We invite public comments on approaches for determining the base cost differentials between domestic and non-domestic PPE items.

[196] In this context, we define ''resiliency'' in a manner consistent with the supply chain characteristics described by Executive Order 14017: *https://www.federalregister.gov/documents/2021/03/01/2021-04280/americas-supply-chains.*

[197] N95 and NIOSH Approved are registered certification trademarks of the HHS in the U.S. and several other countries.

TABLE 79: DOMESTIC PPE ITEMS BEING CONSIDERED WITH BASE COST DIFFERENTIALS AND QUALIFYING CRITERIA

Eligible PPE Item	Domestic Differential Per Single Item	Required Compliance
Filtering Facepiece Respirators	$0.38	- NIOSH-approved - ASTM Respirator Fit Capability Standards
Isolation gowns	$0.82	- FDA Compliance - AAMI Standards
Nitrile exam gloves	$0.05	- FDA Compliance - ASTM Standards

In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the most appropriate framework for determining if NIOSH-approved surgical N95 FFRs were considered domestic for purposes of the separate payment is the Berry Amendment (87 FR 72039 through 40). The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the U.S. Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225–7002, and the provision at 252.225–7002–1 states DoD cannot acquire specified ''items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the U.S.'' With limited exceptions, the entire production process of an affected product, from the production of raw materials to the manufacture of all components to final assembly, must be performed in the U.S.[198]

However, given that the inputs and constituent materials of some potentially eligible domestic PPE products (such as nitrile gloves) are not wholly defined by the Berry Amendment, we are considering defining domestic for purposes of this potential payment policy using the Make PPE In America Act domestic content requirements for Federal procurement contracts outlined in section 70953 of the Infrastructure Investment and Jobs Act. This statute defines American-made PPE as ''personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.'' Those statutory requirements, which apply to procurement of PPE by the U.S. Departments of Health and Human Services, and Veterans Affairs, and Homeland Security, require the procurement of PPE, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the U.S. This Act is similar to the Berry Amendment but broader in the scope of PPE products it covers. PPE manufacturers are generally familiar with its requirements. The aforementioned NIOSH-approved FFRs that demonstrate compliance with the ASTM Respirator Fit Capability Standard, medical gloves in compliance with FDA requirements and conforming to ASTM standards, and gowns in compliance with FDA requirements conforming to AAMI standards eligible for Federal procurement would also be considered domestic for purposes of this potential policy and would therefore be eligible for the potential payment. On an annual basis, in connection with manufacturers' attestations of eligible domestic PPE, a specific exception for NBR for nitrile gloves would be specified if applicable.

D. Potential Eligible Domestic Essential Medicines and Cost Differentials

The report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment,* as developed by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) with the Advanced Regenerative Manufacturing Institute's (ARMI's) Next Foundry for American Biotechnology, prioritized 86 essential medicines [199] from the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs, as developed under the Executive Order by the U.S. Food and Drug Administration (FDA).[200]

The ARMI List is a prioritized list of 86 medicines that are either critical for minimum patient care in acute settings or important for acute care with no comparable alternatives available. The medicines included in the ARMI List were considered, by consensus, to be most critically needed for typical acute patient care. In this context, acute patient care was defined as: rescue use or lifesaving use or both (that is, Intensive Care Units, Cardiac/Coronary Care Units, and Emergency Departments), stabilizing patients in hospital continued care to enable discharge, and urgent or emergency surgery. Development of the ARMI List focused on assessing the clinical criticality and supply chains of small molecules and therapeutic biologics. The development of the ARMI List was informed by meetings with multiple key pharmaceutical supply chain interested parties (for example, manufacturers, group purchasing organizations, wholesale distributors, providers, pharmacies), surveys and workshops with groups of clinicians and industry interested parties, public feedback on the Executive Order 13944 List (provided during a public comment period starting in October 2020), and other research. As discussed in section XXII.B., we previously finalized a separate payment under the IPPS to small, independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of one or more of the ARMI List's essential medicines.

For this potential payment policy, we are considering including certain FDA-approved medicines from the ARMI List

[198] Congressional Research Service: Buying American: Protecting U.S. Manufacturing Through the Berry and Kissell Amendments: *sgp.fas.org/crs/misc/R44850.pdf.*

[199] Hereinafter referred to as the ''ARMI List'' or ''ARMI's List.''

[200] *https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs.*

which have existing U.S. FDF production, and do not contain API from countries listed on the ''foreign adversaries'' list at 15 CFR 791.4.[201] In developing the potential list of eligible essential medicines, we prioritized non-substitutable sterile injectables and generic antibiotics as per the prioritization framework developed by ASPR and Federal supply chain security offices, including within HHS and the DoD. Scheduled drugs, which are already predominantly manufactured domestically, as well as branded drugs were not considered in developing the potential list of eligible essential medicines. All drugs included in the potential list have also been subject to shortage within the previous decade.[202] The priority matrix used for drug selection in developing the potential list of eligible essential medicines under consideration is shown in Table 80:

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[201] *https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-E/part-791/subpart-A/section-791.4.*

[202] Shortages listed on ASHP database: *https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=All.*

TABLE 80: PRIORITY MATRIX FOR DRUG SELECTION IN DEVELOPING THE POTENTIAL LIST OF ELIGIBLE ESSENTIAL MEDICINES

	Critical Role	Shortage History
ACYCLOVIR	Essential for managing viral infections, particularly herpes-related infections, which can complicate other diseases, especially in immunocompromised individuals.	Shortages due to spikes in demand during viral outbreaks and disruptions in manufacturing. Issues such as limited raw material availability and regulatory compliance have also contributed.
Top prescribed penicillin-class antibiotics (AMOXICILLIN, AMPICILLIN, PENICILLIN G, PIPERACILLIN/TAZOBACTAM)	Broad-spectrum antibacterial crucial for treating a variety of infections, including those secondary to viral diseases.	Shortages have been driven by manufacturing delays, increased demand during respiratory illness seasons, and quality control problems. The complex production process and dependency on specific raw materials exacerbate these issues.
ATROPINE SULFATE	Used in surgery to stabilize breathing and heart rate, and as an antidote for nerve agents.	Recent shortages due to discontinuations.
AZITHROMYCIN	Macrolide antibiotic prescribed to treat bacterial infections including pneumonia.	Current shortage due to increased demand and API shortages.
CEFEPIME	Cephalosporin antibiotic used to treat a variety of bacterial infections.	Prone to multi-year shortages, now resolved.
CEFTRIAXONE	Cephalosporin antibiotic used for a variety of infections, including against both gram-positive and gram-negative organisms.	Prone to shortages due to increased demand, manufacturing delays, and discontinuations.
DOXYCYCLINE	Broad spectrum antibiotic effective against a range of bacterial infections.	Prone to occasional shortages over previous decade.
EPINEPHRINE	First-line treatment for anaphylaxis, severe asthma attacks, and cardiac arrest, making it indispensable in emergency settings.	Shortages due to production delays, increased demand during allergy seasons, and supply chain disruptions. The EpiPen shortage in 2018 highlighted the vulnerability of epinephrine supply chains.
LEVOFLOXACIN	Broad-spectrum fluoroquinolone antibiotic reserved for severe, hard-to-treat bacterial infections, and effective for penetrating deep tissues.	Prone to recent shortages due to discontinuations.
LINEZOLID	Oxazolidinone antibiotic effective against multidrug-resistant infections.	Prone to multi-year recent shortages.
MEROPENEM	Carbapenem antibiotic used to combat increased challenges with multidrug resistant infections.	Shortages due to increased demand.
METHYLPREDNISOLONE ACETATE and METHYLPREDNISOLONE SODIUM SUCCINATE	Corticosteroid vital for reducing severe inflammation and treating autoimmune reactions. It has been used extensively in managing severe COVID-19 cases to reduce cytokine storms.	Shortages of methylprednisolone have been linked to increased demand during pandemics, manufacturing issues, and raw material shortages. During the COVID-19 pandemic, its use in treating severe cases led to significant supply challenges.

	Critical Role	Shortage History
VALGANCICLOVIR	An antiviral medication used to prevent and treat Cytomegalovirus (CMV) in immunocompromised individuals, such as organ transplant recipients and people with AIDS.	Oral powders prone to recent shortages due to product discontinuations.
VANCOMYCIN HCL	Vancomycin is critical for treating severe Gram-positive bacterial infections, including MRSA. Infections with antibiotic-resistant bacteria are a significant risk during pandemics when healthcare systems are overwhelmed.	Shortages due to manufacturing disruptions, increased demand during infectious disease outbreaks, and issues with raw material supply. During the early 2010s, there were notable shortages due to increased global demand and the rise in antibiotic-resistant infections.

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As previously noted, we are seeking comment regarding whether the methodology for determining the amount of the payment adjustment under this potential policy should be based on the use of standardized cost differentials for eligible categories of domestic essential medicines. For each eligible essential medicine, we are seeking comment regarding whether it would be appropriate to use two separate possible base cost differentials, depending on whether both the FDF and API for the drug are manufactured domestically, or just the FDF is manufactured domestically. Each drug's base cost differential could be subject to change on an annual basis to reflect inflation and changing pharmaceutical prices over time. We include in Table 81 a list of potential base cost differentials derived from economic analysis of wholesale acquisition costs and informed by public comments, consultations with pharmacists and government procurement specialists, and available literature to estimate costs of domestic production (including a 2022 study by ASPR that found domestic API is around 12 times more expensive than foreign API, and several studies identifying domestic generic costs as 35 to 50 percent higher than generics in India and China [203]). We invite public comments on approaches for determining the base cost differentials between domestic and non-domestic essential medicines.

The cost differential for a given drug dosage would be relative to each particular drug's unit of measurement, referred to here as base dosage. For instance, amoxicillin's base dosage is a single 500 mg capsule; this means that the domestic cost differential for reimbursement would be $0.12 per 500 mg amoxicillin if the drug is made in the U.S. with non-U.S. API, and $0.25 per 500 mg amoxicillin if the drug is made in the U.S. with U.S. API. If a hospital purchases a bottle of 100 capsules of amoxicillin and each individual capsule contains 1 gram of amoxicillin, then the purchased drug dosage (1000 mg) divided by the drug base dosage (500 mg) would lead to a multiple of 2x per capsule, or 200x for the whole bottle. The NDC as used by the hospital would correspond to the entire bottle of 100 amoxicillin capsules, and would equate to a differential separate payment to the hospital of $25 for U.S. FDF only. Similarly, if a 150 ml vial contains 100mg/5ml of linezolid, the purchased drug dosage is 3 gm linezolid which is a multiple of 3x over the base dosage listed in the Table 81 of 1 gm.

All combination drugs containing the eligible drug molecules would be acceptable for a potential separate payment adjustment, based only on the dosage of eligible molecules (see Table 81 for examples).

Using the drug base dosage to calculate the differential separate payment amounts would have three primary benefits over alternative methodologies. First, it would provide flexibility with respect to new market entrants because the base rate would correspond to a product category as a whole, rather than a particular item. Second, this approach would be more resistant to gaming than alternative approaches because it does not rely on manufacturer submitted prices or temporary market conditions that are more liable to capture idiosyncratic factors, such as opportunistic price reporting, unrepresentative market conditions at the time of measurement, or atypically exquisite packaging. Lastly, it would be more transparent from the standpoint of hospitals, which would be able to determine the amount of separate payment for any NDC by applying the payment formula using the publicly available file of eligible products by NDC.

Specifically, we are considering the following domestic essential medicines for inclusion with the following base cost differentials and drug base dosages:

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[203] Lu, Z.J.; Shih, Y.-C. T. Re-Shoring of Generic Drug Global Supply Chain: An Exploratory Economic Analysis. Preprints 2026, 2026021157. *https://doi.org/10.20944/preprints202602.1157.v1;* Mark Abdoo, Douglas Throckmorton. 2020. ''COVID–19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process—06/02/2020.'' FDA. June 4, 2020. *https://www.fda.gov/news-events/congressional-testimony/covid-19-and-beyond-oversight-fdas-foreign-drug-manufacturing-inspection-process-06022020;* Shireesh Ambhaikar, Shantaram Shenai, V. Govindarajan, Pavan Gajare, P. K. Kulkarni, Shankar Suryanarayanan, Christopher Peterson, *et al.* 2025. ''Differences in the Cost of Manufacturing Pharmaceuticals in India for Differently Regulated Markets: A Comparative Analysis.'' MedRxiv (Cold Spring Harbor Laboratory), April. *https://doi.org/10.1101/2025.04.16.25325941.*

TABLE 81: DOMESTIC ESSENTIAL MEDICINES BEING CONSIDERED WITH BASE COST DIFFERENTIALS AND DRUG BASE DOSAGES

Eligible Drug Molecule	Drug Base Dosage	Base Cost Domestic Differential: U.S. FDF + non-U.S. API	Base Cost Domestic Differential: U.S. FDF + U.S. API
ACYCLOVIR	500 MG	$1.50	$ 6.00
AMOXICILLIN	500 MG	$0.12	$ 0.25
AMPICILLIN	500 MG	$0.07	$ 0.62
ATROPINE SULFATE	1 MG	$0.95	$ 7.20
AZITHROMYCIN	500 MG	$0.95	$ 2.88
CEFEPIME	1000 MG	$0.25	$ 2.29
CEFTRIAXONE	1000 MG	$0.11	$ 0.96
DOXYCYCLINE	100 MG	$1.30	$ 8.20
EPINEPHRINE	1 MG	$0.35	$ 3.15
LEVOFLOXACIN	5 MG	$0.27	$ 2.85
LINEZOLID	1000 MG	$1.40	$10.07
MEROPENEM	1000 MG	$0.85	$1.94
METHYLPREDNISOLONE ACETATE	100 MG	$0.54	$5.70
METHYLPREDNISOLONE SODIUM SUCCINATE	1000 MG	$1.80	$7.42
PENICILLIN G	1000 MG; 1.67 million units	$0.29	$2.10
PIPERACILLIN / TAZOBACTAM	500 MG	$0.30	$1.20
VALGANCICLOVIR	100 MG	$0.30	$0.57
VANCOMYCIN HCL	500 MG	$2.75	$6.05

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If we were to adopt such a policy, we would expect to add additional drugs in the future, increasing the number of drugs until the list eventually includes all non-scheduled generic drugs with domestic FDF production on the latest ARMI List. We would also expect that we may account for the production location of pharmaceutical precursors or key starting materials in addition to API and FDF locations.

For these essential medicines, we are considering that an essential medicine would be domestic if the country of origin is the U.S., where ''country of origin'' is defined through incorporation by reference as ''substantial transformation'' of the final dosage form (or the Active Pharmaceutical Ingredient) via 19 CFR 134.1(b). This is identical to the standard used by U.S. Customs and Border Protection, and thus represents a familiar definition for the pharmaceutical industry. This regulation defines ''country of origin'' as the country of manufacture, production, or growth of any article of foreign origin entering the U.S. The regulation also specifies that further work or material added to an article in another country must effect a substantial transformation in order to render such other country the ''country of origin.'' ''Substantial transformation'' is defined by the International Trade Administration to mean that the good underwent a fundamental change in form, appearance, nature, or character.[204] Under this approach, articles manufactured, produced, or grown in the U.S., or that otherwise undergo a substantial transformation in the U.S. would have a domestic country of origin for purposes of the potential payment.

[204] For more information, see: *https://www.trade.gov/rules-origin-substantial-transformation.*

E. Public File of Potential Eligible Domestic PPE and Potential Eligible Domestic Essential Medicines

Under this potential policy, manufacturers of potentially eligible domestic PPE and essential medicines would voluntarily submit annual attestations to HHS that their products meet our domestic definitions. The annual attestations for potentially eligible domestic essential medicines would need to include country-of-origin information for FDF and API, as applicable, that demonstrates that the product was either wholly manufactured, produced, grown, or otherwise substantially transformed in the U.S. Repackaging, on its own, would not be interpreted as passing the ''substantial transformation'' test. For domestically produced drugs whose API is not produced domestically, submitters would attest that the API's country of origin was not a country on the ''foreign adversaries'' list at 15 CFR

791.4 in order to be eligible. The annual attestations from PPE manufacturers would have to demonstrate that the product was in compliance with the ''Make PPE in America'' standards for domestic procurement, with the exception of NBR. We believe manufacturers are uniquely positioned to provide this information. We would welcome public feedback on these approaches to determining eligibility for domestic PPE and essential medicines for purposes of this potential payment policy, including whether alternatives to ''country of origin'' would be more appropriate for determining eligibility for domestic essential medicines, such as identifying the specific FDA-registered facilities responsible for producing the FDF and API.

Under this potential policy, HHS would compile the information provided by manufacturers and create an annual file of eligible domestic products and domestic cost differential estimates, including the NDC or UDI for the product, as applicable, manufacturer name, and part number. This public file would be intended to provide hospitals with a simple, reliable reference for identifying eligible domestic products and the estimated domestic cost differentials.

F. Potential IPPS Approaches to a Separate Voluntary Payment Adjustment for the IPPS Share of the Additional Resource Costs of Procuring Eligible Domestic PPE and Eligible Domestic Essential Medicines

As discussed previously in section XXII.B., we are requesting public comments on a potential separate payment adjustment under the IPPS for the additional resource costs hospitals incur when procuring domestically manufactured items. Based on a review of comments received on the ANPRM, we are considering using our authority under section 1886(d)(5)(I) of the Act to establish a voluntary separate IPPS payment adjustment for the IPPS share of the additional resource costs incurred by hospitals in procuring eligible domestic PPE and essential medicines, as discussed in greater detail in this section. To further support the strategic policy goal of sustaining a level of supply resilience for eligible domestic PPE and essential medicines that are critical to protect the health and safety of personnel and patients, consistent with the existing surgical N95 FFRs policy, we are considering if this potential IPPS payment adjustment should not be budget neutral.

High-quality domestic PPE and essential medicines are generally more expensive than foreign-made ones, especially those produced by manufacturers with less mature manufacturing quality systems.[205] These higher prices primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in other countries, where most PPE and molecular precursors of pharmaceuticals are made, and high investment requirements to maintain mature manufacturing quality systems. These higher prices result in higher marginal costs for hospitals for procuring domestically made PPE and essential medicines. As discussed in the ANPRM (91 FR 3854), an ASPR review of publicly available individual and wholesale prices for both domestic and non-domestic nitrile gloves on manufacturer websites shows that the price of domestically manufactured nitrile gloves is approximately 1.5 to 3 times that of non-domestically manufactured nitrile gloves. A similar ASPR review of the publicly available prices of API from domestic and non-domestic sources reveals that domestic API are, on average, approximately 12 times as expensive as non-domestic alternatives. As previously discussed, we are requesting public comments on a potential separate payment adjustment under the IPPS for the IPPS share of the additional resource costs hospitals incur when procuring domestic PPE and essential medicines. We are also seeking feedback on potential approaches to calculating that separate payment, including the approaches discussed in this section.

One approach we are considering proposing in future rulemaking is a claims-based payment approach (Approach 1) and another is a cost-report payment approach (Approach 2). We first discuss the potential approaches as applied to domestic essential medicines and then discuss them as applied to domestic PPE as tracking domestic PPE use at the IPPS patient level may not be possible for hospitals, although we seek public input on this issue. To the extent tracking domestic PPE use at the IPPS patient level may not be possible for hospitals, we discuss two potential options for an allocation methodology under Approach 2 as applied to domestic PPE (Approach 2a and Approach 2b) that we might consider for future rulemaking.

Under Approach 1 as applied to domestic essential medicines, the claims processing system would use the domestic cost differentials discussed in section XXII.D. to automatically calculate and pay the separate IPPS payment adjustment based on the domestic NDCs and units of those NDCs for eligible domestic essential medicines furnished to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the IPPS claim for that IPPS stay.

Under Approach 2 as applied as applied to essential medicines, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing individually on its IPPS claims. The payment is the same under either approach, but the hospital would not need to submit the NDCs on the claim under Approach 2. As with the current N95 policy, hospitals could request interim biweekly payments under Approach 2 and would be reconciled at cost report settlement. Biweekly payment amounts would be determined by the Medicare Administrative Contractor, consistent with existing policies and procedures using an estimate of the annual reimbursable amount for the year divided into 26 equal payments.

For PPE, to the extent that a hospital can track its use of domestic PPE for individual IPPS inpatients as it can for domestic essential medicines, Approach 1 and Approach 2 would operate similarly for domestic PPE as they would for domestic essential medicines. Under Approach 1, the claims processing system would use the domestic cost differentials discussed in section XXII.C. to automatically calculate and pay the separate IPPS payment adjustment based on the amount of eligible domestic PPE used in furnishing services to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the IPPS claim for that IPPS stay.

To implement this approach, we would create three new billing codes for this purpose: a billing code for eligible domestic N95 FFRs, a billing code for eligible domestic gloves, and a billing code for eligible domestic gowns.

Under Approach 2, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing it individually on its IPPS claims. The payment is the same under

[205] U.S Department of Health and Human Services: Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States, April 2024: *https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.*

either approach (if domestic PPE use is tracked by the hospital at the IPPS patient level under Approach 2, such as by UDI for the product), but hospitals would not need to submit new PPE billing codes on the claim under Approach 2.

To the extent tracking domestic PPE use at the IPPS patient level may not be possible for a hospital, a reasonable allocation methodology would need to be used under Approach 2 to allocate the aggregate amount of domestic PPE purchased by the hospital to IPPS inpatients. We discuss two potential options for an allocation methodology under Approach 2 that we might consider for future rulemaking. Under either potential allocation option, a hospital would report on its cost report the aggregate amount of eligible domestic FFRs purchased, the aggregate amount of eligible domestic gloves purchased, and the aggregate amount of eligible domestic gowns purchased. We also discuss an illustrative example of how each approach might work for the domestic FFRs purchased by a hospital.

Under the first allocation option (Approach 2a), we could use the domestic cost differentials discussed in section XXII.C. and the amount of each type of eligible domestic PPE purchased to calculate the total domestic differential costs incurred by the hospital. To allocate a portion of the total domestic differential costs to IPPS inpatients for purposes of making a separate payment under Approach 2a, we would use the same method and cost data already reported on the hospital cost report that is used under the current N95 FFRs policy. Specifically, the separate payment would be calculated by multiplying the total domestic differential costs by the following fraction (Fraction 1):

- Total Medicare Part A hospital inpatient costs as reported on the cost report in Worksheet D–1 Part II, line 49,[206] divided by
- Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services as reported on the cost report in Worksheet C Part I line 202 column 5.

An alternative allocation approach (Approach 2b) could be to determine, for each category of PPE, a reasonable upper bound on the amount of eligible domestic PPE used in furnishing services to IPPS inpatients. Under this approach, in addition to reporting the aggregate amounts of eligible *domestic* FFRs, eligible *domestic* gloves, and eligible *domestic* gowns purchased, a hospital would report the aggregate amounts of *total* FFRs, *total* gloves, and *total* gowns purchased—irrespective of whether the FFRs, gloves, and gowns are domestic or non-domestic.

Under Approach 2b, we would first proxy the *inpatient* portion of the *total* amount purchased for each category of PPE. In other words, because the total amount purchased by the hospital was used to furnish outpatient and inpatient services, we first need to proxy the portion that was used to furnish inpatient services. We seek public input on potentially using the hospital revenue information on Worksheet G–2 (or suggestions for other alternatives, revenue based or otherwise) to proxy the portion of the total amount purchased for each PPE category that was used to furnish inpatient services.[207] If CMS were to use revenue, we would multiply the total purchased for each PPE category by the following fraction (Fraction 2) calculated from existing cost report information:

- The sum of the inpatient revenue reported on Worksheet G–2, Part I, column 1 (Inpatient), lines 1,16, and 18, divided by
- The sum of the total revenue reported on Worksheet G–2, Part I, column 3 (Total), line 28.

Having proxied the *inpatient* portion of each PPE category, CMS could then proxy an upper bound on the *IPPS inpatient* portion of each PPE category by multiplying by a fraction (Fraction 3) that represents the portion of the hospital's inpatient services furnished to Medicare inpatients relative to all inpatients, calculated from existing cost report information as:

- The sum of the Medicare inpatient days reported on Worksheet S–3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable, divided by
- The sum of the inpatient days reported on Worksheet S–3, Part I, column 8 (Total All Patients), lines 1, 8 through 12, and subscripts as applicable.

The result of this calculation for each PPE category would be the estimated upper bound on the eligible domestic FFRs, gowns, and gloves, respectively, used in furnishing services to IPPS inpatients.

For each PPE category, we would then multiply the upper bound by the domestic cost differential discussed in section XXII.C. to establish an IPPS limit for the separate payment to the hospital for that category of eligible PPE.

Using these IPPS limits, the separate payment to a hospital under Approach 2b would be calculated as the domestic cost differentials discussed in section XXII.C. multiplied by the aggregate amount of each type of domestic PPE purchased by the hospital, not to exceed the IPPS limit for that category of PPE for that hospital.

For purposes of illustrating the differences between Approach 2a and Approach 2b, we provide a hypothetical calculation of the separate IPPS payment under each approach for domestic FFRs purchased by General Hospital (GH). This calculation uses the following assumptions regarding GH's FFR purchases and cost report: (1) GH purchased 1 million FFRs; (2) 300,000 of those FFRs were domestic; (3) GH's total Medicare Part A hospital inpatient costs represent 10 percent of its total costs (Fraction 1); (4) GH's inpatient revenue represents 35 percent of its total revenue (Fraction 2); and (5) GH's IPPS days represent 25 percent of its total inpatient days (Fraction 3). The last three assumptions are approximately equal to the median values of those percentages across all IPPS hospitals based on cost report data.

Under Approach 2a, GH would report on its cost report the 300,000 domestic FFRs purchased by the hospital.

Using the potential domestic differential unit cost for FFRs of $0.38 as discussed in Section XXII.C., the total domestic differential incurred by the hospital is $114,000, which is equal to the 300,000 domestic FFRs purchased times the $0.38 domestic differential unit cost.

Using the fact that GH's total Medicare Part A hospital inpatient costs represent 10 percent of its total costs (Fraction 1), the separate IPPS payment under Approach 2a would be $11,400, which is equal to 10 percent of the $114,000 total domestic differential.

Alternatively, under Approach 2b, GH would report on its cost report the 1 million total FFRs purchased and the 300,000 domestic FFRs purchased.

Using the fact that GH's inpatient revenue represents 35 percent of its total revenue (Fraction 2), CMS would proxy the portion of the 1 million FFRs used in furnishing services to inpatients as 350,000 FFRs, which is equal to 35 percent of the 1 million total FFRs.

Using the fact that GH's IPPS days represent 25 percent of its total inpatient days (Fraction 3), CMS would calculate an upper bound on the number of those 350,000 inpatient FFRs used in furnishing services to *IPPS*

[206] Include the inpatient costs as reported in Worksheet E, Part A, lines 55, 55.01, and 56, if applicable.

[207] Because ancillary costs for all payers are not cleanly subdivided on the cost report between inpatient and outpatient, we are considering using inpatient and outpatient revenue for this purpose.

inpatients as 87,500 FFRs, which is equal to 25 percent of the 350,000 inpatient FFRs.

Using the potential domestic differential unit cost for FFRs of $0.38, CMS would calculate the IPPS payment limit as $33,250, which is equal to the 87,500 FFRs times the $0.38 domestic differential unit cost.

CMS would compare the total domestic differential of $114,000 (calculated the same as under Approach 2a) with the IPPS payment limit of $33,250 and the separate payment would be the lower of the two. In this illustrative example, the separate payment to GH under Approach 2b would be $33,250 because the total domestic differential of $114,000 exceeds the IPPS payment limit.

In summary, in this illustrative example GH would receive a separate IPPS payment of $11,400 under Approach 2a or alternatively a separate payment of $33,250 under Approach 2b.

G. Maximum Annual Amount of Aggregate Payments

Regardless of the payment approach, in conjunction with any such potential policy, we believe it may be prudent to establish an appropriate maximum annual amount of aggregate separate payments that would be available (*e.g.* $500 million or $1 billion) across all IPPS hospitals. To implement such an approach, we could prospectively allocate shares of this aggregate amount to individual hospitals before the start of the fiscal year. If the actual separate payment to a hospital for the fiscal year exceeds its allocated maximum amount, the excess amount would be reconciled at cost report settlement, as the payment for that hospital's excess cost would be considered still bundled into the MS–DRG payment and not separately payable. One potential mechanism for allocating the amount to individual hospitals would be the Medicare inpatient days as reported on Worksheet S–3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable. A hospital's share of the Medicare inpatient days aggregated across all hospitals would be multiplied by the maximum annual amount of aggregate separate payment in order to determine its allocated amount. For example, if the maximum annual amount of aggregate separate payment under this potential policy were $1 billion in a given fiscal year and a hospital's share of aggregated Medicare inpatient days was 0.03 percent based on historical cost reports, then the prospectively determined allocated maximum amount for that hospital for that fiscal year would be $300,000 (=$1 billion * 0.03 percent).

H. Solicitation of Additional Options: Domestic PPE and Essential Medicines

In addition to the approaches described earlier, we solicit general input on additional options from the public. Comments that include detailed information on economic impacts, timing, potential statutory authorities, and a discussion of trade-offs with respect to such options are especially useful to CMS. We are also requesting comment on the operational feasibility and difference of the approach for PPE versus essential medicine of the different aspects of the potential policy. We also seek comment and applicable data regarding current domestic production capacity, manufacturers' ability to expand output, expected expansion timelines, and barriers to scaling production. Please include references to research and data in comments where appropriate.

We note that because the current statutory authority for the existing payment adjustment under the OPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 FFRs (section 1833(t)(2)(E) of the Act) requires those payments to be budget neutral (87 FR 72042, 72268 through 72269), we are not considering expanding and revising the current OPPS N95 policy. Instead, we are considering sunsetting the existing surgical N95 FFRs policy, and also considering simultaneously prospectively removing the associated OPPS budget neutrality adjustment while we explore alternative outpatient approaches for the future.

We also note that after consideration of public feedback on the ANPRM, we are no longer exploring, at this time, a new ''Secure American Medical Supplies'' friendly designation or a new structural quality measure as part of the Hospital IQR Program.

XXIII. Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data

A. Background

Since January 1, 2021, CMS has required each hospital operating in the United States to provide clear, accessible pricing information online about the items and services they offer in two ways: (1) as a comprehensive machine-readable file (MRF) and (2) via a consumer-friendly display. The data we require hospitals to disclose in the MRF serves as a critical resource for users, including employers, researchers and innovators, who may be leveraging the data with the goal of stimulating competition, generating new insights, and driving down healthcare costs. In parallel, the consumer-friendly display empowers consumers seeking healthcare services by making it easier to shop and compare prices across hospitals. Through past rulemaking cycles, requests for information (RFIs), interested parties' listening sessions, and evidence gathered from our compliance process, we continue to identify paths to further refine the hospital price transparency regulations.

The White House issued Executive Order 14221, ''Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information'' on February 25, 2025 (90 FR 11005). Pursuant to this Executive Order, we will ''continue to promote universal access to clear and accurate healthcare prices'' and ''identify opportunities to further empower patients with meaningful price information.'' We are committed to providing consumers with the information needed to make informed decisions about their healthcare, and on November 21, 2025, we issued the CY 2026 OPPS/ASC final rule with comment period to further advance this commitment (90 FR 53448). In the CY 2026 OPPS/ASC final rule with comment period, we finalized changes to the hospital price transparency regulations to help ensure that hospitals provide meaningful, accurate information about the amount they charge for healthcare items and services. We required hospitals to make their MRFs more useful and comparable by publishing actual dollar-based pricing data. Specifically, when a payer-specific negotiated charge is based on a percentage or algorithm, hospitals are required to encode the median, 10th percentile, and 90th percentile allowed amounts (as defined by CMS at 45 CFR 180.20), along with the number of claims used to calculate those figures, using remittance data from the prior 12 to 15 months. We also required hospitals to attest that their MRFs are true, accurate, and complete and that the hospital has included all applicable payer-specific negotiated charges in dollars that can be expressed as a dollar amount; and for payer-specific negotiated charges that cannot be expressed as a dollar amount in the MRF or are not knowable in advance, the hospital has provided in the MRF all necessary information available to the hospital for the public to be able to derive a dollar amount. Furthermore, we

required that the attestation identify a senior official designated to oversee the encoding of true, accurate, and complete data. Lastly, we finalized a requirement for hospitals to include their Type 2 National Provider Identifier(s) to improve standardization across hospitals. These changes went into effect January 1, 2026, with enforcement of these requirements starting April 1, 2026.

B. MRF RFI

We continue to make meaningful progress in standardizing the MRF to lay a strong foundation for transparency and consistency, and we believe that further enhancements to the format and content of the MRF will build on this progress to increase the utility and comparability of the data. We also continue to gain experience with the recent changes finalized in the CY 2026 OPPS/ASC final rule with comment period and continue to assess the extent to which they achieve the objectives outlined in Executive Order 14221. To inform potential enhancements, we have sought feedback from interested parties. On May 22, 2025, we posted the CMS Hospital Price Transparency Accuracy and Completeness RFI on the CMS Hospital Price Transparency website. The feedback gathered from this RFI further emphasized the importance of standardization of data within the MRF to promote accuracy and completeness. Responses also informed CMS' development of additional checks during our compliance review of MRFs. In addition, since the issuance of the CY 2026 OPPS/ASC final rule with comment period, we have received additional suggestions from users of the MRF (innovators, researchers, employers and consumers) through our hospital price transparency mailbox regarding ways to further standardize and improve the MRF data.

Over time, we have introduced several free text data elements (data elements in which unstructured, narrative information is entered) within the MRF and have required hospitals to encode a variety of supporting standard charge information within these data elements. This includes the requirement to encode a description of the standard charge methodology in a free text data element if 'other' is selected as the valid value for the methodology as well as the requirement to encode an explanation in a free text data element when the allowed amount calculations are required but there is no remittance data to perform those calculations. However, we have received feedback from interested parties that valuable contextual information in these free text fields can be difficult for MRF users to interpret or parse. We have specifically received feedback regarding the need for more standardization of outlier provisions and additional contract terms, including, for example, outlier contract provisions that provide additional reimbursement for cases with exceptionally high costs, stop-loss contract clauses which provide additional reimbursement when a patient's treatment costs exceed a specific pre-negotiated threshold, rate-tiering arrangements where payers have categorized hospitals into different tiers based on cost and quality, and carve-out provisions which separate high-cost specialized services from standard bundled rates. Some interested parties noted that these provisions are common contracting practices between hospitals and payers, and that requiring hospitals to report these clauses in a more standardized format would help MRF users better understand when a standard charge applies, and circumstances in which it may not apply. Through compliance reviews, we have observed that this information is not uniformly encoded across hospital MRFs.

We seek interested parties' feedback about whether outlier, stop-loss, rate-tiering, and carve-out provisions are considered payer-specific negotiated charges at the item or service level, in which case they are already required to be encoded in the algorithm data element for each item or service, or whether they are more appropriately considered general contract provisions that apply broadly. When such provisions apply broadly across items and services, we are interested in feedback about specific requirements for standardization of such complex contracting methodologies that would facilitate hospital reporting of accurate and complete information. We have recently issued guidance and examples on how to encode the payer-specific negotiated charge algorithm data element, including the disclosure of outlier information, to support standardization and comparability of this information.[208] However, given the importance of such provisions in hospital contracts and evidence gathered from our experience with compliance reviews and interested parties' feedback, which has shown the need to more clearly indicate whether and when such provisions apply in the MRFs, we anticipate providing additional guidance to support even more clear and accurate reporting of this information and proposing additional requirements through future notice and comment rulemaking.

Interested parties have also identified challenges arising from variations in the name of a payer or a plan across hospitals' MRFs which makes it hard to identify the payer-specific negotiated charge for a specific payer-plan combination and makes comparison across hospitals more difficult. For example, we have seen variations in plan names such as Blue Cross, BlueCross, BC, and BCBS. Interested parties have provided a number of recommendations on how CMS should require more standardization including: publishing a standardized list of the top payer names, requiring a payer or plan unique identifier, for example, a tax identification number or employer identification number, and requiring additional clarifying information like product type and plan type.

Based on our observations while monitoring hospital compliance with the hospital price transparency requirement, as well as assessing recommendations from MRF users, we recognize the importance of requiring more standardization in the MRF to increase the utility of the data and, thereby, increasing competition. As such, we are seeking information from the public on how to strengthen the transparency and usability of the MRFs. Specifically, we welcome public comment on the areas of consideration outlined below:

1. Increasing Transparency of Outlier Provisions and Additional Contract Terms

- What information is needed for users of the MRF to fully understand contract terms related to outlier payments, stop-loss, rate-tiering, carve-outs, and other adjustments that occur across hospital items and services?
- How are hospitals currently reporting contract terms for outlier payments, stop-loss, rate-tiering, carve outs or other adjustments in the MRFs? Are the current formats sufficient for conveying these and other important contract terms? If not, what changes to the current formats, such as separate data elements, would be advised to accommodate the disclosure of such contract terms in a standard manner?
- Do outlier and carve-out contract terms typically apply to individual services, a category of services, or across the entire contract? Should rate-tiering standard charge information be reflected in the payer-specific negotiated charge?
- What additional contracting or payment adjustments affect payer-specific negotiated charges at the item

[208] *https://www.cms.gov/files/document/hospital-price-trasparency-faqs-encoding-algorithms.pdf.*

or service level, across items and services, or at the contract level, and should that information be encoded in the current data elements provided? If not, what changes to the current formats would be advised to capture this information in a standard manner?

2. Standardization To Enhance Utility of the MRF

- Are there challenges in parsing and categorizing the free text fields when analyzing MRFs? If so, what parameters or requirements would facilitate parsing and categorizing free text fields?
- Are there categories of information or topics consistently included in free text fields that may be standardized through the addition of new data elements? If so, what topic areas should be considered?
- Are there additional contract methodologies that should be reflected as valid values in the MRF, outside the current valid values of fee schedule, capitation, per diem, case rate and other?
- Should CMS require more structured reporting of payer, plan, product, network, and employer (as applicable) information across hospital MRFs, and if so, which elements should be required? Are there existing identifiers for payers and plans, to which hospitals have access, that should be incorporated in the MRF?
- What additional information should we consider to enhance the utility and comparability of the MRF data?

C. Consumer-Friendly Display Request for Public Comment

In the final rule that appeared in the November 27, 2019, **Federal Register** (84 FR 65524) titled ''Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates: Price Transparency Requirements for Hospitals to Make Standard Charges Public'' (the CY 2020 HPT final rule), we finalized the requirement for hospitals to display 300 total items and services, 70 of which CMS specified, in a consumer-friendly display. We allowed hospitals to choose the method to do so, either in a shoppable services file or using a price estimator tool. At the time, we provided limited specifications about the data requirements, allowing hospitals flexibility in the format used to display this information.

While we have not altered these consumer-friendly display requirements since issuing the CY 2020 HPT final rule, in an effort to implement Executive Order 14221 we engaged in a series of listening sessions with consumers, consumer advocacy organizations, hospitals, and price estimator tool developers in June and July 2025. During these sessions, we gathered feedback on how effective the consumer-friendly display options were in supporting access to a real and comparable price. The consumers and consumer advocacy organizations shared the challenges of navigating different hospital consumer-friendly display formats to find meaningful price comparisons, as well as the need for a consistent set of requirements across the shoppable services file and the price estimator tool, as the applicable regulatory requirements differ. So as to streamline and standardize requirements for the consumer-friendly display, some interested parties have recommended that CMS no longer deem hospitals compliant with the consumer-friendly display requirements if they offer a price estimator tool, as provided at 45 CFR 180.60(a)(2). Some interested parties also indicated the platforms and formats of price estimator tools vary widely across hospitals, making it difficult to find and compare information. Given the variability of price estimator tools across hospitals, deeming hospitals compliant with the consumer-friendly display requirements if they offer a price estimator tool may limit CMS' ability to address consumers' requests to increase the comparability and usefulness of this information.

Hospitals, consumers, consumer advocacy organizations, and price estimator tool developers also provided feedback on what additional contextual information is important to the consumer to understand a real price, for example, knowing whether the price displayed includes facility or professional service charges. Interested parties from hospitals also indicated that consumers want to know what services are and are not included in the price displayed, as well as the ancillary services that would be billed with the shoppable service. Further, interested parties offered suggestions on how to go beyond standardizing data formats, suggesting a requirement to post more comprehensive information, such as standard service packages, inclusive of standard codes and ancillary services.

In addition, and as mentioned above, in the CY 2020 HPT final rule, we required hospitals to display 70 CMS-specified items and services as part of the total 300 items and services. Since the initial requirement, we have heard feedback from interested parties that some of these items and services may not be particularly useful to consumers or are not universally applicable across all hospitals, such as the add-on CPT code 29826 for shaving of shoulder bone using an endoscope, which may not be considered a shoppable service by consumers or furnished by all hospitals subject to the hospital price transparency requirements. We have also received feedback that some of the required items and services may be out-of-date as this list has not been updated since the CY 2020 HPT final rule. Interested parties have offered suggestions about items and services that may be better suited for the CMS-specified items and services.

Finally, we frequently observe, through compliance reviews, that there are differences between the data in a hospital's consumer-friendly display and MRF for the same items and services. Specifically, we have noted that standard charges in a hospital's consumer-friendly display do not always match the standard charges for the same items and services listed in the hospital's MRF. We are seeking feedback to better understand the circumstances leading to differences in the information across the two formats. Furthermore, a few interested parties, particularly consumer advocates, have observed that hospitals are able to provide information about discounted cash prices in their price estimator tool, even where there is no information about discounted cash prices encoded in the hospital's MRF. We are seeking clarification to better understand why a hospital would be able to provide information about a discounted cash price in the price estimator tool, yet attest in their MRF, by not encoding the information, that they have not established a discounted cash price for that item or service.

From our interactions with consumers, hospitals, and price estimator tool developers, we understand the need to strengthen the comparability of the data included in the consumer-friendly display to enhance consumers' ability to shop for care and obtain pricing information in advance of scheduled services. As such, we are seeking information from the public on how to enhance the comparability of the consumer-friendly display data to inform future rulemaking. Specifically, we welcome public comment on the following questions:

- Should we revisit the number and types of CMS-specified shoppable services? What are the advantages and disadvantages of increasing or decreasing the number of shoppable services? Are there specific shoppable services that CMS should include,

exclude, or update on the list of 70 CMS-specified items and services?

- What would be the advantages and/or disadvantages of requiring hospitals to submit a shoppable services file? Alternatively, what would be the advantages and/or disadvantages of removing the deemed compliance for the price estimator tools? Does the current incongruity in how hospitals display shoppable services, with some posting a shoppable services file and others utilizing a price estimator tool, make it more difficult for consumers to actually compare prices for shoppable services across different hospitals? What positive or negative effects would consumers experience if the price estimator tool alone were no longer considered compliant?
- For hospitals that satisfy the consumer-friendly display requirements through a price estimator tool, what mechanisms could be used to make the underlying data available in a separate file?
- Are there circumstances in which the standard charges in a hospital's shoppable services file would not match the information for the same items and services listed in the hospital's MRF? Why would a hospital be able to provide a discounted cash price in its price estimator tool but not in its MRF?
- Which data elements are important for consumers to make comparisons between hospitals? Would a standard shoppable services file template make the information more comparable? How could a shoppable services file indicate the ancillary services that are included in or excluded from the price?
- How should hospitals present ancillary items, implants, and bundled services so consumers better understand total expected costs? What approaches most effectively distinguish included versus excluded services?
- What additional information should we consider to enhance the comparability of the consumer-friendly display data between hospitals?

XXIV. Collection of Information Requirements

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 the 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

1. Background

In sections XIV. and XV. of this proposed rule, we discuss the proposed requirements for the Hospital Outpatient Quality Reporting Program. The Hospital Outpatient Quality Reporting Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54029 through 54037) for detailed discussions of the previously finalized Hospital Outpatient Quality Reporting Program ICRs which are currently under review for approval under OMB control number 0938–1109 (expiration date June 30, 2026).

In this proposed rule, we propose to: (1) remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) incorporate electronic clinical quality measures (eCQMs) into the existing validation process for chart-abstracted measures beginning with eCQM data from the CY 2027 reporting period affecting the CY 2030 payment determination; (3) reduce the validation selection pool from 500 to up to 400 HOPDs beginning with validation affecting the CY 2030 payment determination; and (4) remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation noncompliance, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination.

Additionally, as part of our proposal to incorporate eCQMs into the existing validation process for chart-abstracted measures beginning with CY 2027 eCQM data affecting the CY 2030 payment determination, we would: (1) modify the number of chart-abstracted cases required for validation from 12 per quarter to a maximum of 8 per quarter per measure beginning with validation affecting the CY 2030 payment determination; (2) replace the previously finalized 2-year validation cycle with a 3-year validation cycle, where hospitals selected for validation based on CY 2027 data affecting the CY 2029 payment determination would not be selected again for validation of the same data affecting the CY 2030 payment determination; (3) determine eCQM validation scores using the same methodology currently used to score chart-abstracted measure validation; (4) revise the policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval; and (5) extend the educational review process established for chart-abstracted measure validation to eCQM validation.

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the Hospital Outpatient Quality Reporting Program by utilizing the Bureau of Labor Statistics (BLS) median hourly wage rate for Medical Records Specialists (90 FR 54029). Specifically, we used the industry-specific wage for Medical Records Specialists working in ''general medical and surgical hospitals'', as this categorization aligns the closest with the Hospital Outpatient Quality Reporting Program care setting. The most recent data from BLS' May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of $28.59 per hour for Medical Records Specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[209] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is 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 ($28.59 × 2 = $57.18) to estimate total cost burden is reasonably accurate. Accordingly, unless otherwise specified, we calculate cost burden to hospitals using a wage plus benefits estimate of $57.18 per hour throughout the discussion in this section of this proposed rule for the

[209] U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at *https://data.bls.gov/oes/#/industry/622100/2025. Accessed: May 18, 2026.*

Hospital Outpatient Quality Reporting Program.

In the CY 2026 OPPS/ASC final rule with comment period, our burden estimates assumed that approximately 3,200 hospital outpatient departments (HOPDs) will report data to the Hospital Outpatient Quality Reporting Program (90 FR 54029). For this proposed rule, based on the most recent available data from the CY 2026 Hospital Outpatient Quality Reporting Program payment determination, we estimate that 3,000 HOPDs will report data to the Hospital Outpatient Quality Reporting Program for the CY 2027 reporting period/CY 2029 payment determination and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

As discussed in section XIV.B. of this proposed rule, we propose removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. For this measure, HOPDs are required to abstract data from patient charts as well as report the measure electronically via CMS' Hospital Quality Reporting (HQR) system. According to the current Hospital Outpatient Quality Reporting Program Specifications Manual, the sample size requirement for HOPDs with populations of 900 patients or less is 63 cases annually, and the requirement for HOPDs with populations of greater than 900 patients is 96 cases annually.[210] To be conservative, we base our burden estimates on an estimate of 96 cases per HOPD annually. Under OMB control number 0938–1109, the currently approved burden is 2.92 minutes (0.049 hours) per case for chart-abstraction and 10 minutes (0.167 hours) per HOPD to report the measure via the HQR. Therefore, we estimate that this proposal would result in a decrease in burden for all 3,000 HOPDs of 14,612 hours [(0.049 hours x 96 cases x 3,000 HOPDs) + (0.167 hours x 3,000 HOPDs)] at a savings of $835,514 (14,612 hours x $57.18) beginning with the CY 2027 reporting period.

[210] CMS. (2025). Hospital OQR Program Specifications Manual Release Notes version 19.0. Available at *https://qualitynet.cms.gov/files/69274c02ec892eacec2209b5?filename=OQR_SpecManual_v19.0a.pdf.*

3. Information Collection Burden Estimate for the Proposed Validation of eCQMs Beginning With Validation of CY 2027 Data Affecting the CY 2030 Payment Determination

As discussed in section XV.D. of this proposed rule, we propose to incorporate eCQMs into the Hospital Outpatient Quality Reporting Program's existing validation process for chart-abstracted measures. We assume HOPDs would only need to upload one PDF file per case to CMS' HQR system, and therefore estimate a burden of 1 minute (0.067 hours) per case per HOPD and propose to validate up to 32 eCQM cases annually from four calendar quarters of eCQM data (up to 8 cases × 4 quarters) for each eCQM with mandatory reporting, starting with validation of CY 2027 eCQM data affecting the CY 2030 payment determination. For purposes of estimating burden in this proposed rule, we assume 400 HOPDs would be selected for validation as discussed in section XXIV.A.4. of this proposed rule. If the proposed reduction of the validation selection pool from 500 to 400 HOPDs is not finalized in the CY 2027 OPPS/ASC final rule with comment period, we will revise our burden estimates in that final rule with comment period using the requirement for selection of 500 HOPDs currently approved under OMB control number 0938–1109. We note submission of medical documentation would occur in the CY immediately following the CY of the data being submitted (for example, CY 2027 data would be submitted in CY 2028, and CY 2028 data would be submitted in CY 2029). For the CY 2028 reporting period, in which HOPDs would be selected for validation of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, we estimate an increase in burden of 213 hours across the 400 HOPDs selected for eCQM validation (0.0167 hours × 4 quarters × 8 cases × 400 HOPDs) at a cost of $12,198 (213 hours × $57.18). For the CY 2029 reporting period and subsequent years, in which HOPDs would be selected for validation of both the STEMI and Emergency Care Access & Timeliness eCQMs, we estimate an increase in burden of 427 hours across the 400 HOPDs selected for eCQM validation (0.0167 hours × 4 quarters × 16 cases × 400 HOPDs) at a cost of $24,397 (427 hours × $57.18).

As discussed in section XV.D. of this proposed rule, we propose policies which would align the proposed incorporation of eCQMs into the existing validation process for chart-abstracted measures beginning with CY 2027 eCQM data affecting the CY 2030 payment determination. Specifically, we propose to modify the number of cases selected for chart-abstracted measure validation under the Hospital Outpatient Quality Reporting Program to align with the proposed number of cases selected for eCQM validation. We also propose to validate up to 32 randomly selected patient cases annually for each chart-abstracted measure. Under these proposals, we would validate up to 32 randomly selected patient cases for chart-abstracted clinical process of care measures (up to 8 cases per quarter), starting with validation of CY 2027 data affecting the CY 2030 payment determination. Submission of medical documentation will occur in the CY immediately following the CY of the data being submitted (for example, CY 2027 data will be submitted in CY 2028). As currently approved under OMB control number 0938–1109, selected HOPDs are required to submit medical documentation for validation for 48 cases (12 cases per quarter), for which we estimate an information collection burden of 15 minutes (0.25 hours) per case, or 12 hours per HOPD (0.25 hours/case × 48 cases). For the CY 2028 reporting period, in which HOPDs would be selected for validation of both the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients and the Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival measures, we estimate the burden associated with these proposals for the 400 HOPDs selected for validation to be 6,400 hours (0.25 hours × 64 cases × 400 HOPDs) at a cost of $365,952 (6,400 hours × $57.18). For the CY 2029 reporting period, in which HOPDs would be selected for validation of only the Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival measures, we estimate the burden associated with these proposals for the 400 HOPDs selected for validation to be 3,200 hours (0.25 hours × 32 cases × 400 HOPDs) at a cost of $182,976 (3,200 hours × $57.18). We discuss the revised information collection burden for all HOPDs selected for chart-abstracted measure validation in section XXIV.A.4. of this proposed rule where we discuss our proposal to modify the validation

selection pool from 500 HOPDs to 400 HOPDs.

Additionally, we propose to replace the previously finalized 2-year validation cycle with a 3-year validation cycle beginning with CY 2027 data affecting the CY 2030 payment determination, under which validation results for a single year of data would be applied to the applicable payment determination 3 years later. Under this proposal, HOPDs selected for chart-abstracted measure validation based on CY 2027 data, affecting the CY 2029 payment determination, would not be selected again for validation of the same data affecting the CY 2030 payment determination. We also propose to determine eCQM validation scores using the methodology currently used to score chart-abstracted measure validation; revise our policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval; and extend the educational review process established for chart-abstracted measure validation to eCQM validation. These proposed changes to the HOPD selection and targeting methodology, validation cycles, scoring methodology, validation scoring, and the educational review process would not affect information collection burden as neither the amount of data nor frequency of data submission is impacted.

4. Information Collection Burden Estimate for the Proposed Modification of the Validation Selection Pool From 500 to up to 400 HOPDs Beginning With Validation of CY 2027 Data Affecting the CY 2030 Payment Determination

As discussed in section XV.D.2.a. of this proposed rule, we propose to reduce the number of hospitals selected at random for validation from 450 HOPDs to up to 200 HOPDs and to increase the number of hospitals selected by targeting criteria from 50 HOPDs to up to 200 HOPDs, for a total of up to 400 HOPDs selected each year beginning with validation of CY 2027 data affecting the CY 2030 payment determination. For purposes of estimating burden in this proposed rule, we assume HOPDs would be required to submit medical record documentation for 32 cases as discussed in section XXIV.A.3. of this proposed rule. If the proposed modification to modify the number of required cases from 48 to 32 cases per chart-abstracted measure is not finalized in the CY 2027 OPPS/ASC final rule with comment period, we will revise our burden estimates using the requirement of 48 cases currently approved under OMB control number 0938–1109. As discussed in section XXIV.A.3. of this proposed rule, for the CY 2028 reporting period, we estimate these two proposals would result in a revised total burden of 6,400 hours (0.25 hours × 4 quarters × 16 cases × 400 HOPDs) at a cost of $365,952 (6,400 hours × $57.18) if finalized; an increase of 400 hours and $22,872 from our currently approved burden of 6,000 hours and $343,080. For the CY 2029 reporting period, we estimate these two proposals would result in a revised total burden of 3,200 hours (0.25 hours × 4 quarters × 8 cases × 400 HOPDs) at a cost of $182,976 (3,200 hours × $57.18) if finalized; a decrease of −2,800 hours and $160,104 from our currently approved burden estimate.

5. Information Collection Burden Estimate for the Proposed Removal of the Requirement for Hospitals To Resubmit Medical Documentation as Part of a Validation Reconsideration Request, Beginning With Data From the CY 2026 Reporting Period Affecting the CY 2028 Payment Determination

As discussed in section XV.E. of this proposed rule, we propose to remove the requirement for HOPDs to resubmit medical documentation as part of their request for reconsideration of validation noncompliance, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination. Instead, we would re-use the medical documentation previously submitted by the HOPD during the validation process. The removal of this requirement would not affect burden related to validation requirements, as reconsideration is an optional administrative activity, and HOPDs would still be required to submit the same number of requested medical records to validate the accuracy of eCQM data (the extent to which data abstracted from the submitted medical record matches the data submitted in the QRDA I file). Additionally, as currently approved under OMB control number 0938–1109, consistent with regulations under the Paperwork Reduction Act of 1995, 5 CFR 1320.4, the burden associated with filing a Reconsideration Request is excluded from our calculation of information collection burden because this collection occurs during the conduct of an administrative action.

6. Summary of Information Collection Burden Estimates for the Hospital OQR Program

Tables 82 through 84 summarize the information collection burden changes under OMB control number 0938–1109. We estimate that the proposed measure removal and modifications to the validation process in this proposed rule would result in a net decrease in information collection burden of 16,985 hours at a savings of $971,221 annually for all 3,000 program-eligible HOPDs beginning with the CY 2029 reporting period/CY 2031 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. With respect to any costs/burdens unrelated to data submission, we refer readers to the regulatory impact analysis in section XXVII. of this proposed rule.

TABLE 82: SUMMARY OF PROPOSED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
	Total Change in Information Collection Burden Hours: -14,612							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-14,612) = **-$835,514**							

TABLE 83: SUMMARY OF PROPOSED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
Implement Updates to Chart-Abstracted Measure Validation	15	4	400	16	8	6,400	6,000	400
Implement eCQM Validation	1	4	400	8	0.533	213	0	213
	Total Change in Information Collection Burden Hours: -13,999							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-13,999) = **-$800,444**							

TABLE 84: SUMMARY OF PROPOSED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2031 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
Implement Updates to Chart-Abstracted Measure Validation	15	4	400	8	8	3,200	6,000	-2,800
Implement eCQM Validation	1	4	400	16	1.067	427	0	427
	Total Change in Information Collection Burden Hours: -16,985							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-16,985) = **-$971,221**							

B. ICRs for the Rural Emergency Hospital (REH) Quality Reporting Program

1. Background

In section XVI. of this proposed rule, we summarize the previously approved requirements for the REH Quality Reporting Program. We are not proposing any changes to the previously finalized REH Quality Reporting Program policies in this proposed rule. The REH Quality Reporting Program is generally aligned with the CMS quality reporting program for HOPDs, known as the Hospital Outpatient Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54037 through 54041) for detailed discussions of the previously finalized REH Quality Reporting Program ICRs, which have been approved under OMB control number 0938–1454 (expiration date December 31, 2026).

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the REH Quality Reporting Program by utilizing the BLS median hourly wage rate for Medical Records Specialists (90 FR 54037). Specifically, we used the industry-specific wage for Medical Records Specialists working in the ''general medical and surgical hospitals'' industry, as this categorization aligns the closest with the REH Quality Reporting Program care setting. The most recent data from BLS' May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of $28.59

per hour for Medical Records Specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[211] 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, doubling the hourly wage rate ($28.59 × 2 = $57.18) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to REHs using a wage plus benefits estimate of $57.18 per hour throughout the discussion in this section of this rule for the REH Quality Reporting Program.

In the CY 2026 OPPS/ASC final rule with comment period, our burden estimates were based on the 38 acute care and critical access hospital conversions to REH status as of April 11, 2025 (90 FR 54037). For this proposed rule, based on the actual number of acute care and critical access hospital conversions to REH status as of April 6, 2026, we estimate that 48 REHs will report data to the REH Quality Reporting Program during the CY 2027 reporting period unless otherwise noted. While the exact number of REHs required to submit data may vary due to status changes to and from an REH, as reiterated in section XVI. of this proposed rule, REHs are required by statute to submit quality data. Therefore, we assume that all 48 REHs will submit data under the REH Quality Reporting Program for the CY 2027 reporting period and subsequent years.

2. Revised Information Collection Burden Estimates for Currently Approved Measures

Our currently approved information collection burden estimates of 464 hours at a cost of $26,532 (using revised wage rates) are based on an estimate of 38 REHs reporting data for the REH Quality Reporting Program. This burden is entirely associated with the reporting of chart-abstracted measures as REHs have the option to report either the Median Time for Discharged Emergency Department (ED) Patients measure or the Emergency Care Access & Timeliness eCQM to meet program requirements, and the estimated burden for the Median Time for Discharged ED Patients is greater than the estimated burden for the Emergency Care Access & Timeliness eCQM. As discussed in section XXIV.B.1. of this proposed rule, we are updating our assumption of the number of REHs that will submit data under the REH Quality Reporting Program from 38 REHs to 48 REHs, an increase of 10 REHs. Our currently approved burden estimates assume that for chart-abstracted measures where patient-level data are submitted directly to CMS, REHs require 2.9 minutes, or 0.049 hours per case per measure to collect and submit the data for each submitted case. We further assume that each REH will abstract and submit data from 63 cases per quarter, for a total of 252 cases per year. Therefore, we estimate each REH requires 12.2 hours (0.049 hours × 252 cases) at a cost of approximately $698 (12.2 hours × $57.18) to collect and report data for the Median Time for Discharged ED Patients measure. For the increase of 10 REHs, we estimate an increase in annual chart-abstraction burden of 122 hours (12.2 hours × 10 REHs) at a cost of $6,976 (122 hours × $57.18).

C. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

1. Background

In sections XIV. and XVII. of this proposed rule, we discuss the proposed requirements for the ASC Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54041 through 54045) for detail regarding the previously finalized ASC Quality Reporting Program ICRs which are currently under review for approval under OMB control number 0938–1270 (expiration date June 30, 2026). We propose to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination.

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the ASC Quality Reporting Program by utilizing the BLS median hourly wage rate for Medical Records Specialists (90 FR 54042). Specifically, we used the industry-specific wage for Medical Records Specialists working in the ''general medical and surgical hospitals'' industry, as this categorization aligns the closest with the ASC Quality Reporting Program care setting. The most recent data from BLS' May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of $28.59 per hour for Medical Records Specialists working in ''general medical and surgical hospitals'' (SOC 29–2072).[212] 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, doubling the hourly wage rate ($28.59 × 2 = $57.18) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to ASCs using a wage plus benefits estimate of $57.18 per hour throughout the discussion in this section of this rule for the ASC Quality Reporting Program.

Based on the most recent analysis of the CY 2026 payment determination data, we found that of the 6,930 ASCs that were actively billing Medicare, 4,399 were required to participate in the ASC Quality Reporting Program. Of the 2,531 ASCs not required to participate in the program, 650 ASCs did so and met full requirements. On this basis, we estimate that 5,149 ASCs (4,399 + 650) will submit data for the ASC Quality Reporting Program for the CY 2027 reporting period/CY 2029 payment determination and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

As discussed in section XIV.B. of this proposed rule, we propose removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. For this measure, ASCs are required to both abstract data from patient charts as well as report the measure electronically via the HQR system. Regarding the number of cases required for chart-abstraction, based on the current ASC Quality Reporting Program Specifications Manual, we estimate that each participating ASC will abstract and submit data for the minimum yearly sample size of 63 annually.[213] Under OMB control number 0938–1270, the currently approved burden is 2.92 minutes (0.049

[211] U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at: *https://data.bls.gov/oes/#/industry/622100/2025.* Accessed: May 18, 2026.

[212] U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at: *https://data.bls.gov/oes/#/industry/622100/2025.* Accessed: May 18, 2026.

[213] *https://qualitynet.cms.gov/files/692dbe71ec892eacec22890b?filename=ASC_v15.0a_FullSpecMan.pdf.*

hours) per case for chart-abstraction and 10 minutes (0.167 hours) per ASC to report the measure via the HQR. Therefore, we estimate that this proposal would result in a decrease in burden for all 5,149 ASCs of 16,753 hours [(0.049 hours × 63 cases × 5,149 ASCs) + (0.167 hours × 5,149 ASCs)] at a savings of $957,937 (16,753 hours × $57.18).

3. Summary of Information Collection Burden Estimates for the ASC Quality Reporting Program

Table 85 summarizes the information collection burden changes for OMB control number 0938–1270. We estimate the proposed measure removal in this proposed rule would result in a decrease in information collection burden of 16,753 hours at a savings of $957,937 annually for all 5,149 program-eligible ASCs beginning with the CY 2027 reporting period/CY 2029 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270. With respect to any costs/burdens unrelated to data submission, we refer readers to the regulatory impact analysis in section XXVII. of this proposed rule.

TABLE 85: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	5,149	63	3.1	0	15,895	-15,895
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Reporting)	10	1	5,149	1	0.167	0	858	-858
	Total Change in Information Collection Burden Hours: -16,753							
	Total Cost Estimate: Updated Hourly Wage ($57.18) x Change in Burden Hours (-16,753) = **-$957,937**							

D. ICRs for the Implementation of Section 6225 of the Consolidated Appropriations Act, 2026 for the Requirements for Provider-Based Status (§ 413.65)

The requirements for a determination that a facility or an organization has provider-based status are in the regulations at § 413.65. Section 6225 of the CAA, 2026 added paragraph (23) to section 1833(t) of the Act, and prohibits Medicare payments for items and services furnished on or after January 1, 2028, unless off-campus outpatient departments of a provider meet certain conditions. New section 1833(t)(23)(A) of the Act requires, as a condition of receiving payment, that off-campus outpatient departments of a provider obtain and bill under separate NPIs and that main providers submit provider-based attestations in accordance with provisions at § 413.65. New section 1833(t)(23)(B)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish a process for each provider with an off-campus outpatient department to submit an initial and subsequent attestation, for the review of each such attestation and for the determination, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether each off-campus outpatient department is compliant with the requirements described in subparagraph (A). In addition, new section 1833(t)(23)(C) defines an ''off-

campus outpatient department of a provider'' for purposes of paragraph (23) as a department of a provider (as defined in § 413.65) that is not located on the campus (also defined in § 413.65) of the main provider or is not within the distance described in such definition of campus from a remote location of a hospital (also defined in § 413.65).

As discussed in greater detail section XX. of this proposed rule, we propose modifications to the provider-based regulations at § 413.65 to implement the new requirements of section 6225 of the CAA, 2026. Among those proposals, we propose to revise § 413.65(b) to add a reference to the new mandatory attestation requirement for an off-campus outpatient department of a provider required by section 6225 of the CAA, 2026 and propose a maximum 5-year timeframe for any subsequent attestation(s). In addition, we propose to establish a standardized attestation form for provider-based determinations, in connection with the provisions of section 6225 of the CAA, 2026, and propose that providers would submit the attestation through a centralized electronic system. The standardized form would replace the current MAC-specific templates. We also propose to eliminate the mandatory requirement for off-campus provider-based facilities or organizations to supply supporting documentation at the time of attestation. Under our proposal, until the standardized form and centralized electronic system are finalized, providers may continue to submit attestations using the current process in satisfaction of section 6225 of the CAA, 2026.

The collection of information requirements for the existing regulations at § 413.65 that govern the requirements for a determination that a facility or an organization has provider-based status is associated with OMB control number 0938–0798 (expiration date December 31, 2027). For the existing attestation requirement in § 413.65(b)(3), OMB has currently approved 2,500 hours of burden at a cost of approximately $327,150 based on accounting for information collection burden experienced by approximately 250 main providers . This estimated burden is based on the expectation that it would take a main provider 10 hours per attestation and each main provider would submit 1 attestation. In this proposed rule, we describe the burden changes regarding collection of information, under OMB control number 0938–0798.

The burden associated with this new attestation requirement continues to be the time for the main provider to report the facility's status to CMS and furnish the necessary documentation to support a provider-based determination. We believe this is reasonable as the information submitted by the provider is typically information that the provider already has regarding their business. However, as discussed in greater detail in section XX.3. of this proposed rule, under the proposal to establish a standardized attestation form for provider-based determinations that providers would submit through a centralized electronic system, we expect there would be a reduction in administrative burden for providers, and a more efficient review process for MACs and CMS. We anticipate that this reduction in administrative burden for providers would decrease the time required to submit each attestation by 25 to 75 percent.

As discussed in section XX.C. of this proposed rule, under existing regulations the attestation process was required only if the main provider sought a CMS determination of provider-based status. However, under the provisions of section 6225 of the CAA, 2026, Medicare payments will be prohibited unless off-campus outpatient departments of a provider meet certain conditions, including that the main provider has submitted an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65 (or a successor regulation); and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. As a result of this new mandatory attestation requirement, we expect there to be an increase in both the number of main providers submitting attestations and the number of attestations submitted by each main provider. Under these new provider-based status attestation requirements, it is estimated that 1,832 main providers would take 5 hours per attestation, and, on average, each main provider would submit 9 attestations for provider based departments. Therefore, we have calculated the burden as follows: 16,488 responses times 5 hours per response = 82,440 burden hours. We believe that an executive officer will be making the attestation because an executive officer is in the best position to have access to the business information required to make the attestation. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2024) at *http://www.bls.gov/oes/current/oes_nat.htm#* for Category 11–0000 for the position of Top Executives, the mean hourly wage for a top executive is $67.24. We have added 100 percent for fringe and overhead benefits, which calculates to $134.48 per hour. We estimate the total cost is $11,086,531 (82,440 hours × $134.48 per hour). The estimated number of attestations has increased due to section 6225 of the CAA, 2026 requiring providers submit attestations for all off-campus provider-based departments. As such, the estimated number of attestations has increased from 250 to 16,488 and the estimated total cost has increased from $327,150 to $11,086,531.

E. ICRs for Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).[214] As part of the CY 2021 OPPS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPS/ASC final rule with comment period, we added an eighth service category to the list of OPD services requiring prior authorization (87 FR 71748, 72224 through 72233.) The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to expand the Botulinum Toxin Injection service category to include additional codes requiring prior authorization. To improve readability and brevity, as we indicated earlier in the preamble, effective dates were removed and the section numbering in the regulatory text was updated. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) have been renumbered as (a)(1) through (8). The additional Botulinum Toxin Injection codes would be added to existing codes located at proposed revised § 419.83 (a)(2) and would require prior authorization beginning for service dates on or after July 1, 2027.

The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by

[214] See also Correction Notice issued January 3, 2020 (85 FR 224).

providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. The request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the additional Botulinum Toxin Injection codes will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (Medicare Administrative Contractor) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task would be 30 minutes, which is equivalent to that for normal prepayment or postpayment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Based on CY 2024 data for the new services, we estimate that annually, there would be 17,699 initial requests mailed during a year. In addition, we estimate there would be 5,808 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated at $117,537 (23,507 mailed requests × $5). We also estimate that an additional 3 hours per provider would be required to attend educational meetings, train staff on what services require prior authorization, and review training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS 2024 rate for Healthcare Support Workers, All Other,[215] we estimate an average median clerical hourly rate of $22.14 with a loaded rate of $44.28. The prior authorization program for the new services will not create any new documentation requirements. Instead, it will only require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff will need to spend more time completing the documentation that will be needed in the absence of the prior authorization policy. The hourly rate reflects the time required for the additional clerical work of submitting the prior authorization request. We believe providers will need to educate their staff on what services are included in the prior authorization process. Following this education, the staff will know which services need prior authorization and will not need additional time or resources to determine whether a service requires prior authorization. We estimate that the total annual number of submissions would be 78,358 (54,851 submissions via fax or electronic means + 23,507 mailed submissions). The annual burden hours for the new services, allotted across all providers, would be 41,555 hours (0.5 hours × 78,358 submissions plus 3 hours × 792 providers for education). The annual burden cost would be $1,957,592 (41,555 hours × $44.28 plus $117,537 for mailing costs). The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval.

Table 86 is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

TABLE 86: TOTAL BURDEN FOR NEW SERVICES

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of Additional Services for Hospital OPD Prior Authorization Process	+41,555	+$1.96 M

* Numbers rounded.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this rule.

XXV. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag, through the use of an asterisk, each drug for which pass-through payment is expiring during the calendar year on a date other than December 31. In the CY 2026 final rule with comment period (90 FR 54058), we retained these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' to include devices, so that the column reads: ''Drug and Device Pass-Through

[215] *https://www.bls.gov/oes/current/oes_nat.htm.*

Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82131), we deleted the column titled ''Copayment Capped at the Inpatient Deductible'' and instead added a new column for ''Adjusted Beneficiary Copayment'' to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also added another column for notes. The ''Note'' column contains multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

In addition, for CY 2024, we updated the format of the OPPS Addenda A, B, and C by adding another column for ''IRA Coinsurance Percentage'' to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the IRA.

In the CY 2026 OPPS/ASC proposed rule, we proposed that for CY 2026 and subsequent years to keep the same format for the addenda A, B, and C, and we did not propose any additional changes for CY 2026 (90 FR 33837). In the CY 2026 OPPS/ASC final rule with comment period, we finalized our policy as proposed (90 FR 54058).

For CY 2027, we are not proposing any changes relating to the format for the addenda A, B, and C.

To view the Addenda to this proposed rule pertaining to CY 2027 proposed payment rates under the OPPS, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices* select ''CMS–1850–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled ''2027 NPRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2027 proposed payment rates under the ASC payment system, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices;* select ''CMS–1850–P'' from the list of regulations. The ASC Addenda to this proposed rule are contained in a zipped folder titled ''2027 NPRM Addendum AA, BB, DD1, DD2, EE, and FF'' in the related links section at the bottom of the page.

XXVI. 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 proposed rule; and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXVII. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2027. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2025 through and including December 31, 2025, and processed through June 30, 2026, and update HCRIS cost report information.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2027, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2027. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. In the CY 2024 OPPS/ASC final rule with comment period, we finalized a policy to extend the 5-year interim period by an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting (88 FR 81960). As discussed in section XIII. of this proposed rule, we propose to extend our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2027). The ASC impacts discussed below reflect our application of the hospital market basket update for CY 2027.

In addition, this proposed rule is necessary to make policy changes for facilities reporting data under the Hospital OQR and ASCQR Programs. The primary objective of these quality reporting programs is to promote higher quality, more efficient health care for Medicare beneficiaries by collecting and reporting on quality-of-care metrics. This information is made available to consumers, both to empower Medicare beneficiaries and inform decision making, as well as to incentivize healthcare facilities to make continued improvements.

B. Overall Impact of Provisions of This Proposed Rule

We have examined the impacts of this 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; and 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, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2027, compared to CY 2026, due to the changes to the OPPS in this proposed rule, will be approximately $1.82 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2027 we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2027 will be approximately $110.9 billion, which is approximately $9.5 billion higher than estimated OPPS expenditures in CY 2026. We also estimate that the proposed 3.0 percentage point adjustment for the 340B Remedy Offset is expected to reduce overall OPPS payments by $2.3 billion in CY 2027. Table 88 of this proposed rule displays the distributional impact of the CY 2027 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2027 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. However, under the proposed 340B drug payment policy for CY 2027, we would pay for drugs acquired through the 340B Drug program at ASP minus 33.4 percent.

We estimate that the proposed update to the conversion factor will increase total OPPS payments by 2.4 percent in CY 2027. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2026 and CY 2027, considering all budget-neutral payment adjustments, proposed changes in estimated total outlier payments, the application of the frontier State wage adjustment, the proposed payment adjustment for imaging without contrast services furnished at excepted off campus PBDs, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act will increase total estimated OPPS payments by 1.9 percent. We note that, as previously discussed in section V.B.7 of this proposed rule, we propose to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies by 3.0 percentage points in CY 2027. We estimate that this reduction would reduce OPPS spending by approximately $2.3 billion in CY 2027.

We estimate the total increase (from changes to the ASC provisions in this proposed rule, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2027 compared to CY 2026, to be approximately $520 million. Tables 89 and 90 of this proposed rule display the redistributive impact of the CY 2027 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2027 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2027 on the CMS website with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.* On the website, select ''Regulations and Notices'' from the left side of the page and then select ''CMS–1850–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 88 of this proposed rule. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Proposal To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider Based Departments (PBDs)

In section X.A. of this proposed rule, we discuss our CY 2027 proposal to control for unnecessary increases in the volume of outpatient services by paying for imaging without contrast services furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, we proposed to pay for HCPCS codes billed with modifier ''PO'' and assigned to and paid through imaging without contrast APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate).

To develop an estimated impact of this policy, we began with CY 2025 outpatient claims data used, for claim lines with HCPCS codes assigned for payment through imaging without contrast APCs 5521 through 5524 and

composite imaging without contrast APCs 8004, 8005, and 8007 that contained modifier ''PO'' because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate, removing a portion of the payment associated with rural sole community hospitals based on our finalized exception for those hospitals. An estimate of the proposed policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2027 Mid-Session review budget approximates the estimated decrease in total payments at $260 million, with Medicare OPPS payments decreasing by $190 million and beneficiary copayments decreasing by $70 million in CY 2027.

This estimate is utilized for the accounting statement displayed in Table 87 of this proposed rule because the impact of this proposed CY 2027 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes in this proposed rule.

We note our estimates may differ from the actual effect of the proposed policy due to offsetting factors, such as changes in provider behavior. We note that by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of imaging without contrast services provided in the excepted off-campus PBD setting.

TABLE 87: ESTIMATED EFFECT OF CHANGES TO IMAGING WITHOUT CONTRAST SERVICES WHEN FURNISHED AT EXCEPTED OFF-CAMPUS PROVIDERS (IN $ MILLIONS)

CY	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027 – 2036
Part B Trust Fund benefits	(260)	(690)	(770)	(840)	(920)	(1,010)	(1,120)	(1,220)	(1,320)	(1,430)	(9,580)
Premium offset	70	170	190	210	230	260	280	310	330	360	2,410
Net Part B Trust Fund impact	(190)	(520)	(580)	(630)	(690)	(750)	(840)	(910)	(990)	(1,070)	(7,170)
Beneficiary cost-sharing	(70)	(180)	(200)	(210)	(240)	(260)	(280)	(310)	(340)	(360)	(2,450)

c. Estimated Effects of OPPS Changes on Hospitals

Table 88 shows the estimated impact of the proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 88, and we discuss them separately below, because CMHCs are paid only for partial hospitalization and intensive outpatient program services under the OPPS and are a different provider type from hospitals. In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269 through 94270), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2027, we propose to maintain the same APC structure and we propose to continue our CY 2026 methodology for calculating rates by applying the 40 percent Medicare Physician Fee Schedule (MPFS) Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2027 is 3.2 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.2 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is a proposed 0.8 percentage point for CY 2027 (which is also the productivity adjustment for FY 2027 in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19850)) resulting in the proposed CY 2027 OPD fee schedule increase factor of 2.4 percent. We are using the OPD fee schedule increase factor of 2.4 percent in the calculation of the proposed CY 2027 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 88 of this proposed rule.

To illustrate the impact of the CY 2027 changes, our analysis begins with a baseline simulation model that uses the CY 2026 relative payment weights, the CY 2026 final OPPS wage indexes that include reclassifications, and the final CY 2026 conversion factor. Table 88 shows the estimated redistribution of the increase or decrease in payments for CY 2027 over CY 2026 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2026 and CY 2027

(Column 2); the wage indexes and the provider adjustments (Column 3); the effect of the proposed payment adjustment for drugs acquired through the 340B Program (Column 4); the combined impact of all of the changes described in the preceding columns plus the 2.4 percent OPD fee schedule increase factor update to the conversion factor (Column 5); the additional estimated impact for the proposed payment adjustment for imaging without contrast services furnished at excepted off campus PBDs (Column 6); the estimated impact taking into account all payments for CY 2027 relative to all payments for CY 2026, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 7).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we propose to maintain the current adjustment percentage for CY 2027. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected passthrough payment for CY 2027 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change, or what proportion of OPPS payments to the hospital are for services compared to drugs), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule redistribute money during implementation will also depend on changes in volume, practice patterns, and the mix of services billed between CY 2026 and CY 2027 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2027 would increase Medicare OPPS payments by an estimated 1.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.8 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers. We note that providers not considered ''new providers'' for purposes of the 340B remedy offset would receive an adjustment to their OPPS payment rates of minus 3.0 percent, which we estimate reduces overall provider payment by 2.9 percent.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 88 shows the total number of facilities (3,471), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2025 hospital outpatient and CMHC claims data to model CY 2026 and CY 2027 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2026 or CY 2027 payment and entities that are not paid under the OPPS. The latter entities include CAHs, IHS and tribal hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,362), excluding the hold harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 39 CMHCs at the bottom of the impact table (Table 88) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals would experience an increase of 0.1, with the impact ranging from a decrease of 0.3 to an increase of 0.4, depending on the number of beds. Rural hospitals would experience a decrease of 0.1 percent overall. Major teaching hospitals would experience a decrease of 0.3 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration, the updates for the wage indexes with the FY 2027 IPPS post-reclassification wage indexes, the rural adjustment, the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year and using a CY 2026 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2027 scaled weights and a CY 2026 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2025 and CY 2027.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2027 changes in wage index policy, discussed in section II.C. of this proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2027, as described in section II.E. of this proposed rule. We modeled a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2027 is 0.88, which is higher than the PCR target adopted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53501). We note that, in accordance with section 16002 of the 21st Century Cures Act, we apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we discuss in section II.F. of this proposed rule.

Column 3 also includes the effects of the proposed COLA factors for providers located in Hawaii and Alaska, which would apply to the non-labor portion of OPPS payments. This proposal is

discussed in detail in section X.C of this proposed rule.

Column 4: Effect of the Proposed Payment Adjustment for 340B Drugs

Column 4 demonstrates the total payment effect of the proposed payment adjustment for drugs acquired under the 340B Program from ASP plus 6 percent to ASP minus 33.4 percent. This column includes both the reduced payment for 340B acquired drugs and the increase to the conversion factor for budget neutrality purposes, which increases payment for all non-drug OPPS services. For rural sole community hospitals, this column shows a 5.7 percent increase, reflecting no payment adjustment for drugs (because these providers are proposed to be exempt from these reductions) and an 8.44 percent increase for non-drug services.

We also note that the proposed 340B drug payment policy described in this column can significantly affect an OPPS provider's estimated CY 2027 payment depending on the proportion of a provider's payment represented by drugs purchased through the 340B Drug Program. For providers that are excepted from the 340B drug payment proposal and for non-340B hospitals, we would generally expect an increase in these providers' estimated 2027 OPPS payments under this column, as they would receive an increase to their non-drug service payments through the budget neutral adjustment to the OPPS conversion factor due to this policy but no change to their drug payments. However, for 340B hospitals, estimated payment changes due to this policy would depend on the volume of 340B drugs the provider furnishes and how that compares to the volume of non-drug services provided by the provider. For most 340B providers, the decreased 340B drug payments will outweigh the increased payments for non-drug services.

Column 5: All Budget Neutrality Changes Combined With the Market Basket Update

Column 5 demonstrates the combined impact of all the proposed changes previously described and the proposed update to the conversion factor of 2.4 percent. Overall, these changes would increase payments to urban hospitals by 1.9 percent and to rural hospitals by 6.4 percent. Rural sole community hospitals would receive an estimated increase of 8.8 percent while other rural hospitals would receive an estimated increase of 2.5 percent.

Column 6—Proposed Off-Campus PBD Imaging Without Contrast Payment Policy

Column 6 displays the estimated effect of our proposed CY 2027 policy to pay for imaging without contrast services assigned to APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 when billed with modifier ''PO'' at a PFS-equivalent rate. We note that the numbers provided in this column isolate the estimated effect of this proposed policy adjustment relative to the numerator of Column 5. Therefore, the numbers reported in Column 6 show how much of the difference between the estimates in Column 5 and the estimates in Column 7 are a result of the off-campus PBD imaging without contrast policy.

Column 7: All Changes With Outlier—Proposed CY 2027 Update

Column 7 depicts the full impact of the proposed CY 2027 policies on each hospital group by including the effect of all changes for CY 2027 and comparing them to all estimated payments in CY 2025. Column 7 shows the combined budget neutral effects of Columns 2 and 3 and 4; the effect of the off-campus provider-based department drug administration policy; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this proposed rule; the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XV. of this proposed rule); and other rule adjustments to the CY 2027 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2026 update (and assumed, for modeling purposes, to be the same number for CY 2027), we included 64 hospitals in our model because they had both CY 2024 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2027 would increase payments to all facilities by 1.9 percent for CY 2027. We modeled the independent effect of all changes in Column 7 using the final relative payment weights for CY 2026 and the proposed relative payment weights for CY 2027. We used the final conversion factor for CY 2026 of $91.415 and a CY 2027 conversion factor of $102.004 discussed in section II.B. of this proposed rule.

Column 7 contains simulated outlier payments for each year. We used the 1 year charge inflation factor used in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19808) of 7.3 percent (1.07310) to increase charges on the CY 2025 claims, and we used the overall CCR in the April 2026 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2026. Using the CY 2025 claims and a 7.3 percent charge inflation factor, we currently estimate that outlier payments for CY 2026, using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,225, would be approximately 1.19 percent of total payments. The estimated current outlier payments of 1.19 percent are incorporated in the comparison in Column 7. We used the same set of claims and a charge inflation factor of 15.1 percent (1.15154) and the CCRs in the April 2026 OPSF, with an adjustment of 0.977497 (91 FR 19808), to reflect relative changes in cost and charge inflation between CY 2026 and CY 2027, to model the proposed CY 2027 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of $7,150. The charge inflation and CCR inflation factors are discussed in detail in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19811).

Overall, we estimate that facilities would experience an increase of 1.9 percent under this proposed rule in CY 2027 relative to total spending in CY 2026. This projected increase (shown in Column 7) of Table 88 of this proposed rule reflects the proposed 2.4 percent OPD fee schedule increase factor, removing the 0.19 difference in estimated outlier payments between CY 2026 (1.19 percent) and CY 2027 (1.0 percent), including the 0.4 percent decrease due to the payment adjusted for drug administration at off campus PBDs, plus 0.12 percent for the change in the pass-through payment estimate between CY 2026 and CY 2027. We estimate that the combined effect of all changes for CY 2027 would increase payments to urban hospitals by 1.3 percent. Overall, we estimate that rural hospitals would experience a 5.9 percent increase as a result of the combined effects of all the changes for CY 2027.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes include a decrease of 3.1 percent for major teaching hospitals and an increase of 6.0 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 3.2 percent.

In our analysis, we also have categorized hospitals by type of

ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.4 percent, proprietary hospitals would experience an increase of 10.3 percent, and governmental hospitals would experience a decrease of 1.3 percent.

Reduction for Providers Subject to the 340B Remedy Offset

In column 8 we have included additional information to account for estimated payment changes in the CY 2027 OPPS for providers subject to the 340B Remedy Offset which we propose will be a 3.0 percent point decrease in CY 2027.

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TABLE 88: ESTIMATED IMPACT OF PROPOSED CY 2027 CHANGES FOR SERVICES PROVIDED IN THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Proposed Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
ALL PROVIDERS *		3,471	0.0	0.1	0.0	2.5	-0.4	**1.9**	-2.9
ALL HOSPITALS		3,362	0.1	0.0	-0.1	2.4	-0.4	**1.8**	-2.9
	(excludes hospitals held harmless and CMHCs)								
URBAN HOSPITALS		2,693	0.1	0.0	-0.5	1.9	-0.4	**1.3**	-2.9
	LARGE URBAN (>1M)	1,274	0.1	-0.2	-0.9	1.4	-0.4	**1.0**	-2.9
	OTHER URBAN (<=1 M)	1,419	0.1	0.1	-0.3	2.3	-0.4	**1.6**	-2.9
RURAL HOSPITALS		669	-0.1	0.5	3.5	6.4	-0.1	**5.9**	-3.0
	SOLE COMMUNITY	329	-0.2	0.7	5.7	8.8	0.0	**8.3**	-3.0
	OTHER RURAL	340	-0.1	0.2	-0.1	2.5	-0.3	**2.0**	-3.0
BEDS (URBAN)									
	0 - 99 BEDS	918	0.4	0.1	4.8	7.9	-0.2	**7.5**	-2.7
	100 - 199 BEDS	741	0.3	0.1	3.0	6.0	-0.3	**5.4**	-2.9
	200 - 299 BEDS	426	0.4	-0.2	2.0	4.6	-0.5	**4.1**	-2.9
	300 - 499 BEDS	377	0.3	-0.1	0.3	2.9	-0.4	**2.3**	-2.9
	500 + BEDS	231	-0.3	0.0	-5.2	-3.2	-0.5	**-4.0**	-2.9

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Proposed Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
BEDS (RURAL)									
	0 - 49 BEDS	315	0.0	0.8	4.6	8.0	0.0	**7.0**	-2.9
	50 - 100 BEDS	196	-0.1	0.3	3.9	6.6	0.0	**6.2**	-3.0
	101 - 149 BEDS	89	-0.2	0.1	2.0	4.4	-0.2	**4.3**	-3.0
	150 - 199 BEDS	39	-0.2	0.7	3.9	6.9	-0.2	**6.2**	-3.0
	200 + BEDS	30	-0.3	0.8	2.7	5.6	-0.2	**5.2**	-3.0
REGION (URBAN)									
	NEW ENGLAND	122	0.0	1.5	-0.7	3.1	-0.6	**2.5**	-3.0
	MIDDLE ATLANTIC	290	0.0	-0.4	-1.2	0.7	-0.8	**-0.1**	-2.9
	SOUTH ATLANTIC	445	0.2	0.0	-0.2	2.3	-0.4	**2.0**	-2.9
	EAST NORTH CENTRAL	410	0.0	-0.8	-0.9	0.6	-0.6	**0.0**	-3.0
	EAST SOUTH CENTRAL	163	-0.1	0.3	-3.0	-0.4	-0.4	**-0.7**	-3.0
	WEST NORTH CENTRAL	173	-0.1	0.9	-1.6	1.6	-0.2	**0.4**	-3.0
	WEST SOUTH CENTRAL	442	0.4	-1.0	1.5	3.3	-0.4	**3.1**	-2.9
	MOUNTAIN	222	0.2	-0.3	1.0	3.4	-0.2	**2.6**	-2.9
	PACIFIC	376	0.2	0.5	-0.4	2.7	-0.2	**2.0**	-2.9
	PUERTO RICO	50	0.5	-1.3	4.8	6.5	0.0	**6.6**	0.0
REGION (RURAL)									
	NEW ENGLAND	20	-0.3	2.5	4.1	9.0	0.0	**8.9**	-3.0
	MIDDLE ATLANTIC	46	-0.3	-0.6	1.3	2.8	-0.2	**2.7**	-3.0
	SOUTH ATLANTIC	109	0.0	0.8	2.9	6.2	-0.4	**6.0**	-3.0
	EAST NORTH CENTRAL	112	-0.1	-0.6	3.4	5.1	-0.2	**5.0**	-2.9
	EAST SOUTH CENTRAL	125	-0.1	0.3	1.0	3.6	-0.1	**3.8**	-3.0

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Proposed Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
	WEST NORTH CENTRAL	73	-0.2	0.8	5.6	8.7	0.0	**8.0**	-3.0
	WEST SOUTH CENTRAL	120	0.4	-0.8	5.0	7.0	-0.2	**7.1**	-3.0
	MOUNTAIN	39	-0.2	1.2	5.6	9.1	0.0	**7.5**	-2.9
	PACIFIC	24	-0.3	3.1	3.2	8.7	0.0	**5.4**	-3.0
	PUERTO RICO	1	2.7	4.7	8.1	19.0	0.0	**11.9**	0.0
TEACHING STATUS									
	NON-TEACHING	1,993	0.3	0.1	3.5	6.4	-0.3	**6.0**	-2.9
	MINOR	905	0.3	0.1	1.1	3.9	-0.4	**3.2**	-3.0
	MAJOR	464	-0.3	-0.1	-4.3	-2.4	-0.5	**-3.1**	-2.9
DSH PATIENT PERCENT									
	0	10	-0.1	-1.3	8.1	9.1	-0.4	**9.0**	-2.5
	> 0 - 0.10	232	0.5	-0.3	6.9	9.7	-0.3	**9.3**	-2.9
	>= 0.10 - 0.16	266	0.5	0.2	6.6	10.0	-0.5	**9.3**	-2.8
	>= 0.16 - 0.23	538	0.5	-0.2	6.4	9.3	-0.5	**9.0**	-2.9
	>= 0.23 - 0.35	1,126	0.0	0.2	-0.7	1.9	-0.4	**1.2**	-2.9
	>= GE 0.35	776	-0.3	-0.1	-5.8	-3.9	-0.3	**-4.5**	-2.9
	DSH NOT AVAILABLE **	414	0.5	-0.2	6.8	9.8	-0.4	**9.5**	-2.8
URBAN TEACHING/ DSH									
	TEACHING & DSH	1,204	0.0	0.0	-1.9	0.4	-0.5	**-0.3**	-2.9
	NO TEACHING/DSH	1,086	0.4	0.0	3.3	6.2	-0.3	**5.8**	-2.9

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Proposed Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
	NO TEACHING/NO DSH	10	-0.1	-1.3	8.1	9.1	-0.4	**9.0**	-2.5
	DSH NOT AVAILABLE**	393	0.6	-0.2	6.8	9.8	-0.4	**9.5**	-2.8
TYPE OF OWNERSHIP									
	VOLUNTARY	1,970	0.0	0.0	-0.5	2.0	-0.4	**1.4**	-2.9
	PROPRIETARY	990	0.9	-0.4	7.4	10.6	-0.2	**10.3**	-2.9
	GOVERNMENT	402	-0.3	0.2	-3.0	-0.8	-0.3	**-1.3**	-2.9
CMHCs		39	-0.5	-1.9	8.1	8.1	0.0	**8.4**	-0.2

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2027 OPPS policies and compares those to the CY 2026 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2027 hospital inpatient wage index. The rural SCH adjustment proposes to continue our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9994because the proposed CY 2027 target payment-to-cost ratio is higher than the CY 2026 PCR target.

Column (4) shows the impact of the proposed 340B drug payment adjustment and the corresponding increase in non-drug service payment.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.4 percent OPD rate update factor (proposed IPPS market basket percentage increase of 3.2 percent reduced by proposed 0.8 percentage point for the productivity adjustment).

Column (6) shows the separate impact of the payment adjustment for imaging without contrast APC services furnished at excepted off campus providers.

Column (7) shows the combined impact of columns 5 and 6, plus additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.

The column for providers subject to the 340B Remedy Offset shows the separate impact of applying the proposed 3.0 percentage point reduction to the OPPS conversion factor update as part of the 340B Remedy Offset.

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**340B Adjustment**	**All Budget Neutral Changes (combined cols 2-4) with Market Basket Update**	**Payment Adjustment for Imaging w/o Contrast at Off Campus Providers**	**All CY 2027 Proposed Changes**	*Impact of Adjustment only for Providers Subject to 340B Remedy Offset*
These 3,471 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.									
We estimate that 3,217 providers would be subject to the reduction to payments that result from the 340B remedy offset.									
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.									

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d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 88 demonstrates the isolated impact on CMHCs, which furnished only partial hospitalization and intensive outpatient program services under the OPPS during CY 2025. As discussed in section VIII.C. of this proposed rule, we propose for CY 2027 to continue paying CMHCs using APCs 5851 through 5854. We modeled the impact of this APC policy, assuming CMHCs will continue to provide the same PHP and IOP care as seen in the CY 2025 claims used for ratesetting in this proposed rule. We did not exclude days with one or two services from our modeling for CY 2027, because our proposed rule policy would pay the per diem rate for APC 5853 for such days in CY 2027. As a result of the proposed PHP APC changes for CMHCs, we estimate that CMHCs would experience a 0.5 percent decrease in CY 2027 payments relative to their CY 2026 payments (shown in Column 2). For a detailed discussion of our proposed PHP and IOP policies, please see section VIII. of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2027 wage index values, which result in an estimated decrease of 1.9 percent to CMHCs.

Column 5 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2027 and the proposed FY 2027 wage index updates, and proposed 340B payment policy, would result in an estimated increase of 8.1 percent.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and decrease for services for which the OPPS payments would fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H. of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18 percent for all services paid under the OPPS in CY 2027. The estimated aggregate beneficiary coinsurance reflects general system adjustments. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII. of this proposed rule. Hospitals, CMHCs, and ASCs will be affected by the changes in this proposed rule. Additionally, the payment policies we established for IOP services affect RHCs and FQHCs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 88. However, the proposed payment amount for OPPS APC 5861 will affect payments to RHCs and FQHCs since under sections 1834(o)(5)(A) and 1834(y)(3)(A) of the Act payment for IOP services in these settings is required to be equal to the payment determined for IOP services in the hospital outpatient department.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of $1.82 billion in program

payments for OPPS services furnished in CY 2027. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in proposed rule would increase these Medicaid beneficiary payments by approximately $40 million in CY 2027. Currently, there are approximately 11.8 million dual-eligible beneficiaries, which represent approximately 40 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 12 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 58 percent Federal payments and 42 percent State payments. Therefore, for the estimated $40 million Medicaid increase, approximately $25 million would be from the Federal Government and $15 million would be from State governments.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this proposed rule.

2. Estimated Effects of CY 2027 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are setting the CY 2027 ASC relative payment weights by scaling the final CY 2027 OPPS relative payment weights by the proposed CY 2027 ASC scalar of 0.809. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 89 and 90.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. In the CY 2024 OPPS/ASC final rule with comment period, we extended this 5-year interim period an additional 2 years through CYs 2024 and 2025. In the CY 2026 OPPS/ASC final rule with comment period, we extended the interim period an additional year through 2026. As discussed in further detail in section XIII. of this proposed rule, we propose an extension of our utilization of the hospital market basket update as the update factor to the ASC payment system for 1 additional year (through CY 2027). Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economywide 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). For ASCs that fail to meet their quality reporting requirements, the CY 2027 payment determinations would be based on the application of a 2.0 percentage point reduction to the hospital market basket update for CY 2027. We calculated the proposed CY 2027 ASC conversion factor by adjusting the CY 2026 ASC conversion factor ($56.322) by 1.0016 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2026 and CY 2027, which includes our policy to limit wage index declines of greater than 5 percent, and by applying the CY 2027 hospital market basket update factor of 2.4 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by a productivity adjustment of 0.8 percentage point). The proposed CY 2027 ASC conversion factor is $57.766 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2027 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2026 and CY 2027 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2027 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as ophthalmology, digestive system, or orthopedic procedures. The combined effect of the final update to the payments on an individual ASC would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the proposed CY 2027 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2024 claims data. Table 89 depicts the estimated aggregate percent change in payment by surgical specialty by comparing estimated CY 2026 payments to estimated CY 2027 payments, and Table 90 shows a comparison of estimated CY 2026 payments to estimated CY 2027 payments for items and procedures that we estimate would receive the most Medicare payment in CY 2026.

In Table 89, we have aggregated the surgical HCPCS codes by specialty group and then estimated the effect on aggregated payment for surgical specialty. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 89.

- Column 1—Surgical Specialty Group indicates the surgical specialty into which ASC procedures are grouped. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2026 ASC Payments were calculated using CY 2025 ASC utilization data (the most recent full year of ASC utilization) and CY 2026 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2026 ASC payments.
- Column 3—Estimated CY 2027 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty that is attributable to the proposed update to ASC payment rates for CY 2027 compared to CY 2026.

As shown in Table 89, for the six specialty groups that account for the most ASC utilization and spending, we

estimate that the proposed update to ASC payment rates for CY 2027 would result in a 1 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 6 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 6 percent increase in aggregate payment amounts for nervous system procedures, a 2 percent decrease in aggregate payment amounts for digestive system procedures, a 5 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 1 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than the proposed 2.4 percent increase, depending on if payment weights in the OPPS APCs after application of the ASC weight scaler that correspond to the applicable services increased or decreased, if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 1 percent decrease in eye surgical procedure payments and a 2 percent decrease in gastrointestinal surgical procedure payments. The decrease in expenditures for these surgical specialties is attributable to the 2.4 percent hospital market basket update being offset by the reduction in the ASC weight scaler. The reduction in the ASC weight scaler from 0.872 in CY 2026 to our proposed 0.809 for CY 2027 is attributable to the increase in device portions under the ASC payment system as a result of the increase in OPPS payment rates for clinical services for CY 2027 and out policy to treat device portions of device-intensive procedures as constant between the OPPS and ASC payment system. The increase in proposed CY 2027 OPPS payment rates for clinical services is a result of the OPPS budget neutrality adjustment from the proposed 340B drug payment policy. Therefore, surgical specialties that predominantly consist of procedures designated as device-intensive under the ASC payment system will see an increase in expenditures greater than the 2.4 percent hospital market basket update whereas surgical procedures that have relatively few device-intensive procedures will see a relatively smaller increase or decrease in CY 2027 expenditures. The increases in expenditures for musculoskeletal, nervous system, and cardiovascular surgical specialties groups is a result of the higher share of device-intensive procedures that are assigned to this surgical specialty group. For estimated changes for selected procedures, we refer readers to Table 89.

TABLE 89: ESTIMATED IMPACT OF THE PROPOSED CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2026 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2026 ASC Payments (in Millions) (2)	Estimated CY 2027 Percent Change (3)
Total	$8,349	2
Eye	$2,120	-1
Musculoskeletal	$2,019	6
Nervous System	$1,580	6
Gastrointestinal	$1,059	-2
Cardiovascular	$635	5
Genitourinary	$365	1

Table 90 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2027. The table displays 30 of the procedures receiving the greatest estimated CY 2026 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2026 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2026 ASC Payments were calculated using CY 2024 ASC utilization (the most recent full year of ASC utilization) and the CY 2026 ASC payment rates. The estimated CY 2026 payments are expressed in millions of dollars.
- Column 4–Estimated CY 2027 Percent Change reflects the percent differences between the estimated ASC payment for CY 2026 and the estimated payment for CY 2027 based on the final update.

TABLE 90: ESTIMATED IMPACT OF THE PROPOSED CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2026 ASC Payment (in millions) (3)	Estimated CY 2027 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,383	-2
27447	Total knee arthroplasty	$529	5
63685	Ins/rplc spi npg/rcvr pocket	$421	15
27130	Total hip arthroplasty	$284	6
45385	Colonoscopy w/lesion removal	$273	-2
45380	Colonoscopy and biopsy	$253	-2
23472	Reconstruct shoulder joint	$215	7
43239	Egd biopsy single/multiple	$174	-2
63650	Implant neuroelectrodes	$161	6
64590	Ins/rpl prph sac/gstr npg/r	$131	8
66991	Xcapsl ctrc rmvl insj 1+	$125	10
64483	Njx aa&/strd tfrm epi l/s 1	$108	-3
66982	Xcapsl ctrc rmvl cplx wo ecp	$103	-2
64635	Destroy lumb/sac facet jnt	$103	-3
29827	Sho arthrs srg rt8tr cuf rpr	$97	36
36902	Intro cath dialysis circuit	$90	-1
64628	Trml dstrj ios bvn 1st 2 l/s	$75	7
64493	Inj paravert f jnt l/s 1 lev	$74	-3
0627T	Perq njx algc fluor lmbr 1st	$73	9
66821	After cataract laser surgery	$67	-2
G0105	Colorectal scrn; hi risk ind	$64	-2
65820	Relieve inner eye pressure	$57	-2
64561	Implant neuroelectrodes	$56	8
64555	Implant neuroelectrodes	$54	10
15823	Revision of upper eyelid	$51	-4
G0121	Colon ca scrn not hi rsk ind	$47	-2
62323	Njx interlaminar lmbr/sac	$44	-2
64721	Carpal tunnel surgery	$42	-3
33285	Insj subsq car rhythm mntr	$41	4
27279	Arthrd si jt perq/min nvas	$40	7

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2027 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the procedures we are finalizing to add to the ASC CPL for CY 2027. First, other than certain preventive services where coinsurance and the Part B deductible are waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will usually be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For those additional procedures that we finalized to designate as office-based in

CY 2027, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPPS and ASC Payment System

As required by OMB Circular A–4 (available on the Office of Management and Budget website at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf,* we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 91, illustrates the classification of expenditures for the CY 2027 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2027 OPD fee schedule increase and the proposed policy for imaging without contrast services furnished at excepted off-campus PBDs. The second accounting statement, Table 92, illustrates the classification of expenditures associated with the 2.4 percent CY 2027 update to the ASC payment system, based on the provisions of the proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 91: ACCOUNTING STATEMENT: CY 2027 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2026 TO CY 2027 ASSOCIATED WITH THE CY 2027 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1.82 billion
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 92: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2026 TO CY 2027 AS A RESULT OF THE PROPOSED CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$170 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$170 million

3. Effects of Proposed Changes in Requirements for the Hospital Outpatient Quality Reporting Program

a. Background

We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54071 and 54072) for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting Program for the CY 2026 reporting period and subsequent years. Of the 2,984 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2026 payment determination for the Hospital Outpatient Quality Reporting Program, we determined that 35 HOPDs did not meet the program requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 47 HOPDs elected not to participate.

b. Impact of CY 2027 OPPS/ASC Proposed Rule Proposals

We propose to: (1) remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) incorporate electronic clinical quality measures (eCQMs) into the existing validation process for chart-abstracted measures beginning with eCQM data from the CY 2027 reporting period affecting the CY 2030 payment determination; (3) reduce the validation selection pool from 500 to up to 400 HOPDs beginning with validation affecting the CY 2030 payment determination; and (4) remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination.

As part of the proposal to incorporate eCQMs into the existing validation process for chart-abstracted measures, we would also update our data validation policies for chart-abstracted measures, including modifying the number of chart-abstracted measure cases required for validation from 12 per quarter to up to 8 per quarter per measure beginning with validation affecting the CY 2030 payment determination.

We refer readers to section ''XXIV. Collection of Information'' of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the Hospital Outpatient Quality Reporting Program for the estimated 3,000 program-eligible HOPDs. As shown in summary Table 84 in section XXIV.A.6. of this proposed rule, we estimate a total information collection and reporting burden net decrease of 16,985 hours at a savings of $971,221 annually associated with our proposals beginning with the CY 2029 reporting period/CY 2031 payment determination compared to our information collection burden estimates which are currently under review for approval under OMB control number 0938–1109 (expiration date June 30, 2026).

In addition to the reduced information collection burden associated with the proposals in this proposed rule, we believe there would be administrative cost savings associated with the proposed removal of the requirement for HOPDs to resubmit medical documentation as part of their request for reconsideration of validation noncompliance. Regarding the proposed incorporation of eCQMs into the existing validation process for chart-abstracted measures, with more than 98 percent of HOPDs eligible to participate in the Hospital Outpatient Quality Reporting Program affiliated with hospital systems that are already familiar with the eCQM validation process under the Hospital Inpatient Quality Reporting Program, we anticipate their experience with eCQM validation for the Hospital Inpatient Quality Reporting Program would minimize the additional costs beyond the information collection burden discussed in section XXIV.A. of this proposed rule associated with eCQM validation by leveraging existing or similar personnel and processes.

We do not believe the remaining proposals would result in any additional economic impact beyond that discussed in section ''XXIV. Collection of Information'' of this proposed rule.

4. Effects of Requirements for the Rural Emergency Hospital (REH) Quality Reporting Program

We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54072 and 54073) for the previously discussed effects of changes to the REH Quality Reporting Program for the CY 2026 reporting period and subsequent years. For the CY 2027 reporting period, we have estimated there will be 48 REHs required to report under the REH Quality Reporting Program based on acute care and critical access hospital conversions to REH status as of April 6, 2026. We note that this estimate is an increase of 10 REHs from our estimate of 38 provided in the CY 2026 OPPS/ASC final rule with comment period, resulting in an increase in total information collection burden for the REH Quality Reporting Program of 122 hours and $6,976 (90 FR 54072). We are not proposing any changes to our previously finalized REH Quality Reporting Program policies in this proposed rule.

5. Effects of Proposed Changes in Requirements for the Ambulatory Surgical Center (ASC) Quality Reporting Program

a. Background

We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54073) for the previously estimated effects of changes to the ASC Quality Reporting Program for the CY 2026 reporting period and subsequent years. Based on the most recent analysis of the CY 2026 payment determination data, we found that, of the 6,930 ASCs that were actively billing Medicare, 4,399 were required to participate in the ASC Quality Reporting Program. Of the 2,531 ASCs not required to participate in the program, 650 ASCs did so and met full requirements. On this basis, we estimate that 5,149 ASCs (4,399 + 650) will submit data for the ASC Quality Reporting Program for the CY 2027 reporting period and subsequent years unless otherwise noted. We note that this estimate is an increase of 559 ASCs from our estimate of 4,590 provided in the CY 2026 OPPS/ASC final rule with comment period (90 FR 54073) due to more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2027 OPPS/ASC Proposed Rule Proposals

We propose to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. We refer readers to section ''XXIV. Collection of Information'' of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the ASC Quality Reporting Program for the estimated 5,149 program-eligible ASCs. As shown in summary Table 85 in section XXIV.C.3. of this proposed rule, we estimate a total information collection and reporting burden decrease of 16,753 hours at a savings of $957,937 annually associated with our proposal for the CY 2027 reporting period/CY 2029 payment determination and subsequent years compared to our information collection burden estimates which are currently under review for approval under OMB control number 0938–1270 (expiration date June 30, 2026). We do not believe this proposal would result in any additional economic impact beyond those discussed in section ''XXIV. Collection of Information'' of this proposed rule.

6. Effects of Addition of New Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[216] As part of the CY 2021 OPPS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, December 29, 2020). Through the CY 2023 OPPS/ASC final rule with comment period, we added an eighth service category to the list of OPD services requiring prior authorization (87 FR 71748, 72224 through 72233, November 23, 2022). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to expand the Botulinum Toxin Injection service category to include additional codes requiring prior authorization. To improve readability and brevity, as we indicated earlier in section XVIII. of this proposed rule, effective dates were removed and the section numbering in the regulatory text was updated. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) have been renumbered as (a)(1) through (8). The additional Botulinum Toxin Injection codes would be added to the existing codes located at proposed revised § 419.83(a)(2) and would require prior authorization beginning for service dates on or after July 1, 2027.

The addition of these services is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the healthcare sector to require prior authorization for these additional codes is dependent on the number of claims affected. Table 94, Overall Economic Impact on the Health Sector, lists an estimate of the overall economic impact on the health sector for the new services. The values populating Table 93 were obtained from the cost reflected in Table 94, Annual Private Sector Costs, and Table 95, Estimated Annual

[216] See also Correction Notice issued January 3, 2020 (85 FR 224).

Administrative Costs to CMS. Tables 94 and 95 combine to convey the overall economic cost impact to the health sector for the new services, which is illustrated in Table 93.

Based on the estimate, the overall economic cost impact is approximately $9.6 million in the first year for the new services. The 5-year impact is approximately $48 million, and the 10-year impact is approximately $95.9 million. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $25 million. We believe there are likely to be other benefits that result from the prior authorization requirement for the new services, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We will solicit public comments on the potentially increased costs and benefits associated with this proposed provision for the new services.

TABLE 93: OVERALL ECONOMIC COST IMPACT ON THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	$1,957,592	$9,787,962	$19,575,924
Medicare Costs	$7,632,439	$38,162,195	$76,324,390
Total Economic Impact to Health Sector	$9,590,031	$47,950,157	$95,900,314

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the proposed rule may change the billing practices of those providers. The purpose of the statute and this proposed rule is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the additional OPD services to be a condition that we must mitigate. We believe that the effect would be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding the new services would offer additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements were met.

b. Anticipated Specific Cost Effects

(1) Private Sector Costs

We do not believe that this proposed rule would significantly affect the number of legitimate claims submitted for the new services. However, we expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the additional services will be equivalent to that of submitting documentation and clerical activities associated with prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 94: ANNUAL PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests- Initial Submissions	41,299	0.5	20,649	$914,351
Fax and Electronic Submitted Requests- Resubmissions	13,552	0.5	6,776	$300,041
Mailed in Requests- Initial Submissions	17,699	0.5	8,850	$391,865
Mailed in Requests- Resubmissions	5,808	0.5	2,904	$128,589
Mailing Costs	23,507	5		$117,537
Provider Demonstration- Education	792	3	2,376	$105,209
Total			41,555	$1,957,592

(2) Administrative Costs to CMS

CMS would incur additional costs associated with processing the prior authorization requests for the new services. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $95, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education, outreach, and system changes.

TABLE 95: ANNUAL ESTIMATED ADMINISTRATIVE COSTS TO CMS

Additional Services	Estimated Annual Administrative Cost
Botulinum Toxin Injections	$7,632,439

(3) Estimated Beneficiary Costs

We expect a reduction in the utilization of the new Medicare OPD services when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although this proposed rule permits utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and, thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

(4) Estimated Benefits

There will be quantifiable benefits for this proposed rule because we expect a reduction in the unnecessary utilization of the new Medicare OPD services subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on a 25 percent savings percentage, we estimate an overall gross savings of $25 million. These savings represent a Medicare benefit from more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the additional OPD services would help ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient, or the patient does not meet the Medicare requirements, would likely be reduced by requiring a provider to submit clinical documentation as part of its prior authorization request.

We solicit comments on the potential additional burden associated with applying prior authorization requirements to these additional botulinum toxin injection codes, including any impacts on providers and beneficiaries.

D. Regulatory Review Cost Estimation

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 this rule. It is possible that not all commenters reviewed this 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 also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $119.10 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is $952.80 (8 hours × $119.10). Therefore, we estimate that the total cost of reviewing this regulation is $2,898,418 ($952.80 × 3,042).

E. 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 governmental jurisdictions. The great majority of 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).)

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. 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.[217] Table 96 shows the number of firms, revenue, and estimated impact per hospital category.

[217] *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.*

TABLE 96: 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	00-499	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	50,000-74,999	276	15,547,026	56,330
622	Hospitals	75,000-99,999	144	11,728,762	81,450
622	Hospitals	100,000+	1,222	1,300,730,378	1,064,427
622	Hospitals	Total	3,136	1,354,538,978	431,932

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_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_6digitnaics_rcptsize_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 97: 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
OPPS Hospitals	3,481	1,605	$1,830	$32,900,000	$20,498
ASCs	6,179	5,560	$170	$59,200,000	$10,647

* Based on the assumptions that small firms represent 46.1 percent of OPPS Hospitals and account for approximately 1.8 percent of total industry revenues, and, small firms represent 90.0 percent of ASCs and account for approximately 34.8 percent of total industry revenues using the SBA size standards,

For purposes of the RFA, approximately half of all hospitals are considered to be small entities. As shown in Table 96, 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.

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. This

proposed rule includes a number of proposed policy changes that can significantly increase or decrease estimated 2027 payments at an individual level, including changes such as the proposed exceptions to the 340B drug payment proposal and the payment adjustment for imaging without contrast services furnished at provider based departments. Based on this impact 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.

Therefore, the Secretary has certified that this proposed rule will have a significant economic impact on a substantial number of small entities.

For example, we estimate that a majority of the 3,481 OPPS providers included in the impact analysis presented in Table 88 would experience average payment increases of approximately 2.0 percent. We attribute those changes primarily to the proposed change in estimated outlier payments, changes in estimated pass through spending, and the proposed OPPS update. Across hospital categories, we estimate that impacts would range from an increase of 8.8 percent for rural sole community hospitals to an estimated decrease of 4.2 percent for hospitals with a DSH patient percentage greater than 35 percent.

As shown in Tables 91 and 92, we estimate that this proposed rule would result in aggregate transfers of approximately $1.82 billion to OPPS providers and $170 million to ASCs. In Table 97, 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 3,481 OPPS providers, approximately 1,605 are small entities. Applying the 1.8 percent revenue share, we estimate that approximately $32.9 million of the OPPS impacts would accrue to small entities, which corresponds to an average impact of approximately $20,498 per small OPPS provider.

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, in the corresponding sections of this proposed rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in the impact analysis of this proposed rule, this rule is expected to generally increase OPPS payments to the approximately 511 small rural hospitals. Therefore, the Secretary has certified that this proposed rule will have a significant impact on the operations of a substantial number of small rural hospitals.

The analyses presented in this section 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.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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 2027, that threshold is approximately $193 million.

This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year.

G. Federalism

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.

We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 88 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease by 1.3 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

H. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''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''. This rule is expected to be an E.O. 14192 regulatory action. We estimated that this rule will generate $6.23 million in annualized cost at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 1, 2026.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. 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), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.65 is amended—

■ a. In paragraph (a)(2) by adding the definition of ''Off-campus outpatient department of a provider'' in alphabetical order;

■ b. By revising paragraphs (b)(3)(ii) and (iii);

■ c. By adding paragraph (b)(6);

■ d. By revising paragraphs (e) introductory text, (g)(1)(i) and (ii), (h) introductory text, and (k).

The additions and revisions read as follows:

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) * * *

(2) * * *

* * * * *

Off-campus outpatient department of a provider means a department of a provider that is not located on the campus of the main provider (as defined in this section) or within 250 yards of a remote location of a hospital (as defined in this section).

* * * * *

(b) * * *

(3) * * *

(ii) If the facility is not located on the campus of the potential main provider or within 250 yards of a remote location of a hospital, the attesting provider would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to maintain documentation of the basis for its attestations to CMS and to furnish such information upon request.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS or its agents will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS or its agents at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

* * * * *

(6) As of January 1, 2028, for each off-campus outpatient department of a provider, excluding those described in paragraphs (m) or (n) of this section, a provider must submit an initial attestation for provider-based status within the 2-year period prior to furnishing services, and a subsequent attestation within a period not to exceed 5 years thereafter.

* * * * *

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider or within 250 yards of a remote location of a hospital must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

* * * * *

(g) * * *

(1) * * *

(i) Any facility or organization that is located on the main hospital campus or within 250 yards of a remote location of a hospital and is treated by CMS under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by CMS under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

* * * * *

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider or within 250 yards of a remote location of a hospital and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

* * * * *

(k) *Temporary treatment as provider-based.* If a provider submits an attestation of compliance with the requirements for provider-based status, as described in paragraph (b) of this section, for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits an attestation until the date that CMS determines that the facility or organization does not meet the provider-based rules. CMS may, at any time, initiate an extended review to validate the attestation of compliance, including through site visits, remote audits, desk reviews, investigations, or any other means CMS determines appropriate. As part of such a review, the provider must submit supporting documentation sufficient to demonstrate compliance with the provider-based requirements set forth in this section, in the form and manner and within the timeframe specified by CMS. Failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of payments as described in this paragraph (k). If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 4. Section 416.171 is amended by revising paragraphs (a)(2)(iii) through (viii) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2027, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2028 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period

ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section was reduced by 2.0 percentage points for ASCs that failed to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2027, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2028 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(v) of this section, was reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2027, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2028 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 6. Adding § 419.23 to subpart B to read as follows:

§ 419.23 Special rule for off-campus outpatient department of a provider.

(a) No payment may be made under this part for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider (as defined in paragraph (b) of this section) unless—

(1) Such department has obtained, and such items and services are billed under, a National Provider Identifier that is separate from such identifier for such provider;

(2) Such provider has submitted an initial attestation for provider-based status in accordance with § 413.65(b)(6) of this chapter; and

(3) After such provider has submitted an initial attestation under paragraph (a)(2) of this section, such provider has submitted a subsequent attestation within the timeframe specified in and in accordance with § 413.65(b)(6) of this chapter.

(b) For purposes of this section, off-campus outpatient department of a provider is defined at § 413.65(a)(2) of this chapter.

■ 7. Section 419.32 is amended by—

■ a. Revising paragraph (b)(1)(iv)(B)(*12*); and

■ b. Adding paragraph (b)(1)(iv)(B)(*13*).

The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*12*) For calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 0.5 percentage point reduction, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs or biologicals, furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later.

(*13*) Beginning in calendar year 2027, a multifactor productivity adjustment (as determined by CMS), and 3.0-percentage point reduction, except that the 3.0-percentage point reduction shall not apply to hospital outpatient items and services furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until the estimated payment reductions made in accordance with paragraph (b)(1)(iv)(B)(*12*) of this section and this paragraph (b)(1)(iv)(B)(*13*) for all applicable hospital outpatient items and services reaches $7.769 billion, as further described in each calendar year's rule.

* * * * *

■ 8. Section 419.43 is amended by adding paragraph (l) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(l) *Cost-of-living adjustment.* An additional adjustment is made for hospitals located in Alaska and Hawaii to account for the higher cost-of-living in those States.

9. Section 419.46 is amended by revising paragraphs (f)(2), (f)(3) introductory text, (f)(4), and (g)(2)(vii) and (viii) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(2) A hospital meets the validation requirements with respect to a calendar year if it achieves:

(i) An overall reliability score of at least 75-percent for chart-abstracted measure validation, as determined by CMS; and

(ii) Beginning with validation affecting the CY 2030 payment determination, an overall reliability score of at least 75-percent for eCQM validation, as determined by CMS.

(3) CMS will select a random sample of up to 200 hospitals, beginning with validation affecting the CY 2030 payment determination, or 450 hospitals, for validation affecting payment determinations prior to CY 2030, for validation purposes, and will select up to an additional 200 hospitals, beginning with validation affecting the CY 2030 payment determination, or 50 hospitals for validation affecting payment determinations prior to CY 2030, for validation purposes based on the following criteria:

* * * * *

(4) Hospitals that are selected and receive a score for validation may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation were incorrectly scored, the corrected validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(2) * * *

(vii) Except as provided in paragraph (g)(2)(viii) of this section, a copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (f)(2) of this section, the hospital must provide:

(A) A written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered; and

(B) Any evidence that supports the hospital's reconsideration request, including, as applicable, copies of patient charts, emails, and other documents. The hospital is not required to resubmit materials previously submitted to CMS unless specifically requested by CMS.

* * * * *

■ 10. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* The following service categories comprise the list of hospital outpatient department services requiring prior authorization:

(1) Blepharoplasty.

(2) Botulinum toxin injections.

(3) Panniculectomy.

(4) Rhinoplasty.

(5) Vein ablation.

(6) Cervical Fusion with Disc Removal.

(7) Implanted Spinal Neurostimulators.

(8) Facet Joint Interventions.

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 11. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 12. Section 427.303 is amended by revising paragraph (b)(1)(iv) to read as follows:

§ 427.303 Determination of total number of billing units.

* * * * *

(b) * * *

(1) * * *

(iv) Separately payable billing units in claim lines billed with the ''TB'' modifier and successor billing modifiers to identify 340B units, for claims with dates of service on or after January 1, 2025.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 13. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 14. Section 488.5 is amended by adding paragraph (a)(21) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(21) For accrediting organizations seeking or maintaining CMS approval of accrediting programs for hospitals, Critical Access Hospitals, and Rural Emergency Hospitals, the application must include a description of the policies and procedures the organization will use to assess compliance with the EMTALA-administrative requirements set forth at § 489.20 (l), (m), (q), and (r) during accreditation and reaccreditation surveys, including—

(i) Procedures for reviewing required EMTALA signage;

(ii) Procedures for verifying that transfer records are maintained and retained for at least 5 years;

(iii) Procedures for verifying the on-call physician lists are maintained as required;

(iv) Procedures for verifying a central log of individuals presenting to the emergency department is maintained as required;

(v) Procedures for reporting identified noncompliance with § 489.20 to CMS in accordance with CMS oversight requirements; and

(vi) Procedures for reporting identified noncompliance with § 489.24 subsequently identified during survey to CMS in accordance with CMS oversight requirements.

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Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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