DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS–1691–P]

RIN 0938–AT28

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2019. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, it proposes a rebasing of the ESRD market basket for CY 2019. This proposed rule also proposes to update requirements for the ESRD Quality Incentive Program (QIP), and to make technical amendments to correct existing regulations related to the CBP for certain DMEPOS. Finally, this proposed rule proposes changes to bidding and pricing methodologies under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program (CBP); adjustments to DMEPOS Fee Schedule amounts using information from competitive bidding for items furnished from January 1, 2019 through December 31, 2020; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that new payment classes for oxygen and oxygen equipment are budget neutral; payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment (DME); and payment methodology revisions for mail order items furnished in the Northern Mariana Islands. This rule also includes a request for information related to establishing fee schedule amounts for new DMEPOS items and services. It also includes Requests for Information on promoting interoperability and electronic healthcare information exchange, and improving beneficiary access to dialysis facility and DMEPOS charge information.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 10, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1691–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. 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–1691–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–1691–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:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

DMEPOS@cms.hhs.gov, for issues related to DMEPOS payment policy.

Julia Howard, (410) 786–8645, for issues related to DMEPOS CBP technical amendments only.

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: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the United States Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates and revisions to the ESRD PPS for CY 2019.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule proposes to update the AKI payment rate for CY 2019.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized under section 1881(h) of the Social Security Act (the Act), and is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This proposed rule proposes a number of updates for the ESRD QIP.

4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP): This rule proposes to revise the DMEPOS CBP by implementing lead item pricing based on maximum winning bid amounts.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP: This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: We are proposing to establish new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. We are also proposing to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

iv. Payment for Multi-Function Ventilators: This rule proposes to establish new rules to address payment for certain ventilators that are subject to the payment rules at section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs: This rule proposes to amend

§ 414.210(g)(7) to indicate that beginning on or after the date that contracts take effect for a national mail order competitive bidding program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under this paragraph would no longer apply.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2019:* The proposed CY 2019 ESRD PPS base rate is $235.82. This proposed amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.5 percent), and application of the wage index budget-neutrality adjustment factor (0.999833), equaling $235.82 ($232.37 × 1.0150 × 0.999833 = $235.82).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2019, we propose to increase the wage index floor, for areas with wage index values below the floor, to 0.5000 and are proposing to update the wage index values to the latest available data.
- *Update to the outlier policy:* We are proposing to update the outlier policy using the most current data, as well as update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2019 using CY 2017 claims data. Based on the use of the latest available data, the proposed FDL amount for pediatric beneficiaries would increase from $47.79 to $47.88 and the MAP amount would decrease from $37.31 to $35.62, as compared to CY 2018 values. For adult beneficiaries, the proposed FDL amount would decrease from $77.54 to $69.73 and the MAP amount would decrease from $42.41 to $40.25. The 1 percent target for outlier payments was not achieved in CY 2017. Outlier payments represented approximately 0.8 percent of total payments rather than 1.0 percent. We believe using CY 2017 claims data to update the outlier MAP and FDL amounts for CY 2019 would increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage. We are also soliciting comment on whether we should expand the outlier policy to include composite rate drugs and supplies.
- *Update to the Drug Designation Process:* We are proposing to update and revise our designation process and expand the transitional drug add-on payment adjustment (TDAPA) to all new drugs, not just those in new functional categories, and change the basis of determining the TDAPA from pricing methodologies under section 1847A of the Act, (which includes ASP +6) to ASP +0.
- *Update to the Low-Volume Payment Adjustment:* We are proposing revisions to the low-volume payment adjustment regulations to allow for more flexibility with regard to attestation dates and cost reporting requirements, as well as updating the requirements for eligibility with respect to certain changes of ownership.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2019. The proposed CY 2019 payment rate is $235.82, which is the same as the base rate proposed under the ESRD PPS for CY 2019.

3. ESRD QIP

This proposed rule proposes a number of new requirements for the ESRD QIP beginning with PY 2021, including the following:

- We are proposing to update the ESRD QIP's measure removal criteria, which we now refer to as ''factors'', so that they are more closely aligned with the measure removal factors we have adopted, or proposed to adopt for other quality reporting and pay for performance programs, as well as the priorities we have adopted as part of the Meaningful Measures Initiative.
- We are proposing to remove four measures: Healthcare Personnel Influenza Vaccination, Pain Assessment and Follow-Up, Anemia Management, and Serum Phosphorus. Removal of these measures would align the ESRD QIP measure set more closely with the priorities we have adopted as part of our Meaningful Measures Initiative.
- We are proposing to make several changes to the domains and domain weights that we use for purposes of our scoring methodology to more closely align the ESRD QIP with the priorities we have adopted as part of our Meaningful Measures Initiative. We are proposing to remove the Reporting Domain from the Program and to move each reporting measure currently in that domain (and not being proposed for removal) to another domain that is better aligned with the focus area of that measure. Additionally, we are proposing that the Patient and Family Engagement/Care Coordination Subdomain and the Clinical Care Subdomain, both of which are currently subdomains in the Clinical Measure Domain, would become their own domains. As a result, the ESRD QIP would be scored using four domains instead of three. Furthermore, we are proposing new domain and measure weights that better align with the priority areas we have adopted as part of our Meaningful Measures Initiative.
- We are proposing to update our policy governing when newly opened facilities must start reporting ESRD QIP data. The proposed policy would require facilities to begin reporting ESRD QIP data beginning with the month that begins 4 months after the month during which the CMS Certification Number (CCN) becomes effective (for example, a facility with a CCN effective date of January 15th would be required to begin reporting ESRD QIP data collected in May). The proposed policy would provide facilities with a longer time period than they are given now to learn how to properly report ESRD QIP data.
- We are proposing to increase the number of facilities that we select for validation under the National Healthcare Safety Network (NHSN) data validation study from 35 to 150 facilities, and to increase the number of records that each selected facility must submit to 20 records for each of the first 2 quarters of CY 2019 (for a total of 40 records). This proposal would improve the overall accuracy of the study.
- We are proposing to convert the current Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data validation study into a permanent program requirement using the methodology we first adopted for PY 2016 because an analysis demonstrated that this methodology produced reliable validation results. We are also proposing that the 10 point deduction for failure to comply with the data request, which was first adopted for PY 2017, would become a permanent program requirement.

This proposed rule also proposes a number of new requirements for the ESRD QIP beginning with PY 2022, including the following:

- We are proposing to adopt the Percentage of Prevalent Patients Waitlisted (PPPW) Measure and to place it in the proposed Care Coordination Measure Domain (NQF #2988).
- We are proposing to adopt the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure (NQF #2988) and to place it in the Safety Measure Domain.

• We are proposing to increase the number of facilities that we select for validation under the NHSN data validation study from 150 to 300 facilities. This proposal would further improve the overall accuracy of the study.

This proposed rule also proposes to set forth new requirements for the ESRD QIP beginning with PY 2024, including the following:

• We are proposing to adopt the Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure and to place it within the proposed Patient and Family Engagement/Care Coordination Domain as a second measure in the proposed Transplant measure topic.

Finally, we are proposing to codify in our regulations several previously finalized requirements for the ESRD QIP by revising § 413.177 and adopting a new § 413.178.

4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP): We are proposing to revise the DMEPOS CBP by implementing lead item pricing based on maximum winning bid amounts. We are proposing to revise the definition of bid to mean an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items. We are proposing to revise the definition of composite bid to mean the bid submitted by the supplier for the lead item in the product category. We are proposing to revise the definition of lead item to mean the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP: We are proposing transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: We are proposing to establish new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. We are also proposing to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

iv. Payment for Multi-Function Ventilators: We are proposing to establish new rules to address payment for certain ventilators that are subject to the payment rules at section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs: We intend to include the Northern Mariana Islands under national mail order competitive bidding programs that become effective on or after January 1, 2019, so we are proposing to amend § 414.210(g)(7) to indicate that beginning on or after the date that contracts take effect for a national mail order competitive bidding program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under this paragraph would no longer apply.

C. Summary of Costs and Benefits

In section XVI of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section XV of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2019 compared to estimated payments in CY 2018. The overall impact of the proposed CY 2019 changes is projected to be a 1.7 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.8 percent increase in payments compared with freestanding facilities with an estimated 1.7 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately $220 million in CY 2019 compared to CY 2018. This reflects a $190 million increase from the payment rate update and a $30 million increase due to the updates to the outlier threshold amounts. As a result of the projected 1.7 percent overall payment increase, we estimate that there would be an increase in beneficiary co-insurance payments of 1.7 percent in CY 2019, which translates to approximately $60 million.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section XVI of this proposed rule displays the estimated change in proposed payments to ESRD facilities in CY 2019 compared to estimated payments in CY 2018. The overall impact of the proposed CY 2019 changes is projected to be a 1.5 percent increase in payments. Hospital-based ESRD facilities and freestanding facilities both have an estimated 1.5 percent increase in payments.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the proposed CY 2019 ESRD PPS base rate would increase by less than $1 million in CY 2019 compared to CY 2018.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the ESRD QIP would be approximately $219 million in PY 2021. The $219 million figure for PY 2021 includes costs associated with the collection of information requirements, which we estimate would be approximately $181 million. For PY 2022, we estimate that ESRD facilities would experience an overall economic impact of approximately $240 million as a result of the PY 2022 ESRD QIP. The $240 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate would be approximately $202 million. Our proposal to add the SWR measure to the ESRD QIP measure set in PY 2024 would not result in additional costs associated with the collection of information requirements because the measure does not use data reported to CROWNWeb.

4. Impacts of the Proposed Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

This rule proposes to base single payment amounts on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS Competitive Bidding Program. The impacts of the rule are estimated by rounding to the nearer 5 million dollars and are expected to cost $10 million in Medicare benefit payments for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The impacts on beneficiary cost sharing is roughly $3 million over this 5-year period. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be $0 million.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished in areas that are currently CBAs and in areas currently not CBAs on or after January 1, 2019. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place as of January 1, 2018, which establish payment for items furnished in CBAs based on fee schedule amounts fully adjusted in accordance with current regulations at 42 CFR 414.210(g). The impacts are expected to cost $1,050 million dollars in Medicare benefit payments and $260 million dollars in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019 and ending December 31, 2020. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to be $45 million dollars and $30 million dollars, respectively. Section 503 of the Consolidated Appropriations Act of 2016 and section 5002 of the Cures Act, added section 1903(i)(27) to the Act, which prohibits federal Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement took effect January 1, 2018. We note that the costs for the Medicaid program and beneficiaries could be higher depending on how many state agencies adopt the higher Medicare adjusted fee schedule amounts for rural areas for use in paying claims under the Medicaid program. We are not able to quantify this impact.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This rule proposes to establish new payment classes for oxygen and oxygen equipment and is estimated to be budget neutral to the Medicare program and its beneficiaries.

iv. Payment for Multi-Function Ventilators

This rule proposes to establish new rules to address payment for certain ventilators that are subject to the payment rules at section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act. The impacts are estimated by rounding to the nearer 5 million dollars and are expected to cost $15 million in Medicare benefit payments and $0 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be $0 million.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs

This change would not have a fiscal impact.

II. Calendar Year (CY) 2019 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous product that is not considered included in the ESRD PPS bundled payment, meaning a product that is used to treat or manage a condition for which there is not an existing ESRD PPS functional category (§ 413.234). The ESRD PPS functional categories represent distinct groupings of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. New injectable or intravenous products that are not included in a functional category in the ESRD PPS base rate are paid for using the TDAPA for a minimum of 2 years, until sufficient claims data for rate setting analysis are available. At that point, utilization would be reviewed and the ESRD PPS base rate modified, if appropriate, to account for these products. The TDAPA is based on pricing methodologies under section 1847A of the Act (§ 413.234(c)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 1, 2017, we published a final rule in the **Federal Register** titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (82 FR 50738 through 50797) (hereinafter referred to as the CY 2018 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2018, the wage index, and the outlier policy, and pricing outlier drugs. For further detailed information regarding these updates, see 82 FR 50738.

B. Provisions of the Proposed Rule

1. Drug Designation Process

a. Protecting Access to Medicare Act of 2014

Section 217(c) of PAMA requires the Secretary to implement a drug designation process for: (1) Determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under such system. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological is no longer oral only and a process to include new injectable and intravenous products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration (FDA). Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). As discussed in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022), effective January 1, 2016, if a new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or intravenous product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biologicals reflected in the base rate.

As we discuss in § 413.234(b)(2), if the new injectable or intravenous product is used to treat or manage a condition for which there is not an

ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the drug is evaluated. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage. Next, the new injectable or intravenous product is paid for using the transitional drug add-on payment adjustment (TDAPA). Then, the new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the TDAPA.

Under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act and is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not for less than 2 years. During the time a new injectable or intravenous product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate would be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

b. Renal Dialysis Drugs and Biologicals Reflected in the Base Rate (ESRD PPS Functional Categories)

As discussed above, in the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized the drug designation process as being dependent upon the functional categories, consistent with our policy since the implementation of the PPS in 2011. We provide a detailed discussion (80 FR 69013 through 69015) on how we accounted for renal dialysis drugs and biologicals in the ESRD PPS base rate since its implementation on January 1, 2011. In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained that in order to identify drugs and biologicals that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biologicals billed on ESRD claims and evaluated each drug and biological to identify its category by indication or mode of action. Categorizing drugs and biologicals on the basis of drug action allows us to determine which categories (and therefore, the drugs and biologicals within the categories) would be considered used for the treatment of ESRD (75 FR 49047). We grouped the injectable and intravenous drugs and biologicals into functional categories based on their action (80 FR 69014). This was done with the purpose of adding new drugs or biologicals with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

Using the functional categorization approach, we established categories of drugs and biologicals that are *not* considered used for the treatment of ESRD, categories of drugs and biologicals that are *always* considered used for the treatment of ESRD, and categories of drugs and biologicals that *may be* used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49049 through 49051). The drugs and biologicals that were identified as *not* used for the treatment of ESRD were not considered renal dialysis services and were *not* included in computing the base rate. The functional categories of drugs and biologicals that are *not* included in the base rate can be found in the CY 2011 ESRD PPS final rule (75 FR 49049). The functional categories of drugs and biologicals that were *always* and *may be* considered used for the treatment of ESRD were considered renal dialysis services and were included in computing the base rate. Subsequent to the CY 2011 discussion about the *always* and *may be* functional categories (75 FR 49050 through 49051), we also discussed these categories in the CY 2016 ESRD PPS final rule (80 FR 69015 through 69018) and clarified the medical conditions or symptoms that indicate the drugs are used for the treatment of ESRD. See Table 1.

TABLE 1—ESRD PPS FUNCTIONAL CATEGORIES

Category	Rationale for association
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	Used to prevent or treat nausea and vomiting related to dialysis. Excludes antiemetics used for purposes unrelated to dialysis, such as those used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications. Use within an ESRD functional category includes treatment for itching related to dialysis.
Anxiolytic	Drugs in this classification have multiple actions. Use within an ESRD functional category includes treatment of restless leg syndrome related to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders.	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat vascular access site pain and to treat pain medication overdose, when the overdose is related to medication provided to treat vascular access site pain.

In computing the ESRD PPS base rate, we used the payments in 2007 for drugs and biologicals included in the *always* functional categories, that is, the injectable forms (previously covered under Part B) *and* oral or other forms of administration (previously covered under Part D) (75 FR 49050). For the oral or other forms of administration for those drugs that are *always* considered used for the treatment of ESRD, we determined that there were oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. Therefore, we included the payments made under Part D for oral vitamin D (calcitriol, doxercalciferol and paricalcitol) and oral levocarnitine in our computation of the base rate (75 FR 49042).

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49051), we explained that drugs and biologicals that *may be* used for the treatment of ESRD may also be commonly used to treat other conditions. We used the payments made under Part B in 2007 for these drugs in computing the ESRD PPS base rate, which only included payments made for the injectable version of the drugs. We excluded the Part D payments for the oral (or other form of administration) substitutes of the drugs and biologicals described above because they were not furnished or billed by ESRD facilities or furnished in conjunction with dialysis treatments (75 FR 49051). For those reasons, we presumed that these drugs and biologicals that were paid under Part D were prescribed for reasons other than for the treatment of ESRD. However, we noted that if these drugs and biologicals paid under Part D are furnished by an ESRD facility for the treatment of ESRD, they would be considered renal dialysis services and not be billed or paid under Part D.

Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) provides the Medicare allowable payments for all of the components of the ESRD PPS base rate for CY 2007, inflated to CY 2009, including payments for drugs and biologicals and the amount each contributed to the base rate, except for the oral-only renal dialysis drugs where payment under the ESRD PPS has been delayed. A list of the specific Part B drugs and biologicals that were included in the final ESRD PPS base rate is located in Table C of the Appendix of the CY 2011 ESRD PPS final rule (75 FR 49205 through 49209). A list of the former Part D drugs that were included in the final ESRD PPS base rate is located in Table D of the Appendix of that rule (75 FR 49210). As discussed in section II.3.d of this proposed rule, the ESRD PPS base rate is updated annually by the ESRD bundled (ESRDB) market basket.

c. Section 1847A of the Social Security Act (the Act) and Average Sales Price (ASP) Methodology Under the ESRD PPS

In the CY 2005 Physician Fee Schedule (PFS) final rule, published on November 15, 2004 (69 FR 66299 through 66302) in the **Federal Register**, we discussed that section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1847A to the Act and established the Average Sales Price (ASP) methodology for certain drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005. The ASP methodology is based on quarterly data submitted to CMS by drug manufacturers. The ASP amount is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of ''best price'' in the Medicaid drug rebate program. Each drug with a healthcare common procedure coding system (HCPCS) code has a separately calculated ASP. To allow time to submit and calculate these data, the ASP is updated with a two-quarter lag.[1]

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment allowance for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the HCPCS code. Section 1847A(b)(1)(B) of the Act also requires that the Medicare payment allowance for a single source drug HCPCS code be equal to the lesser of 106 percent of the ASP for the HCPCS code or 106 percent of the wholesale acquisition cost (WAC) of the HCPCS code.

Section 1847A(c)(4) of the Act further provides a payment methodology in cases were the ASP is unavailable. Specifically Pub. 100–04, Chapter 17, section 20 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/;clm104c17.pdf*) titled ''Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis'', provides guidance on how Medicare Part B pays for drugs and biologicals under section 1847A of the Act and notes that, in the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—the wholesale acquisition cost; or the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals. This publication provides guidance on how Medicare Part B pays for drugs and biologicals under section 1847A of the Act.

In the CY 2018 ESRD PPS final rule (82 FR 50742 through 50743), we discussed how we have used the ASP methodology since the implementation of the ESRD PPS when pricing ESRD-related drugs and biologicals previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations. We adopted § 413.234(c), which requires that the TDAPA is based on the pricing methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such pricing methodologies for new and existing injectable drugs or biologicals that qualify as an outlier service.

d. Proposed Revision to the Drug Designation Process Regulation

As noted above, in prior rulemakings we addressed how new drugs and biologicals are implemented under the ESRD PPS and how we have accounted for renal dialysis drugs and biologicals in the ESRD PPS base rate since its implementation on January 1, 2011. Accordingly, the drug designation process we finalized is dependent upon the functional categories we developed and is consistent with the policy we have followed since the inception of the ESRD PPS. However, since PAMA only required the Secretary to establish a process for including new injectable and intravenous drugs and biologicals, such new products were the primary focus of the regulation we adopted at § 413.234, rather than codifying our full policy for other renal dialysis drugs, such as drugs and biologicals with other forms of administration, including, oral, that by law are included under the ESRD PPS (though oral-only renal dialysis drugs are required to remain outside of the ESRD PPS bundle until CY 2025).

In this proposed rule, we propose to revise the drug designation process regulations at § 413.234 to reflect that the process applies for all new renal

[1] Sheingold, S., Marchetti-Bowick, E., Nguyen, N., Yabrof, K.R. (2016, March). Medicare Part B Drugs: Pricing and Incentives. Retrieved from *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf.*

dialysis drugs and biologicals that are approved regardless of the form or route of administration, that is, new injectable, intravenous, oral, or other route of administration, or dosage form. We note that for purposes of the ESRD PPS drug designation process, use of the term *form of administration* is used interchangeably with *route of administration.* We are proposing these revisions so that the regulation reflects our long standing policy for all new renal dialysis drugs and biologicals, regardless of the form or route of administration, with the exception of oral-only drugs. Specifically, we propose to replace the definition of ''new injectable or intravenous product'' at § 413.234(a), ''an injectable, intravenous, oral or other form or route of administration drug or biological that is used to treat or manage a condition(s) associated with ESRD,'' with a definition for ''new renal dialysis drug or biological,'' to encompass the broader scope of the drug designation process. Under this definition, a new renal dialysis drug or biological ''must be approved by the Food and Drug Administration (FDA) on or after January 1, 2019 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs or biologicals are excluded until January 1, 2025.''

In our proposal to replace the definition of ''new injectable or intravenous product'' in § 413.234(a) with the proposed definition of ''new renal dialysis drug or biological,'' we have included the clause, ''have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures.'' We note that this would be a change from the existing policy of requiring that the new product be assigned an HCPCS code. We are proposing that new renal dialysis injectable or intravenous products are no longer required to be assigned an HCPCS code before the TDAPA can apply, instead we would require that an application has been submitted in accordance with the Level II HCPCS coding procedures. This would allow the application of the TDAPA to the ESRD PPS base rate to happen more quickly than under our current process wherein a lag that occurs when a drug or biological is approved but is waiting for the issuance of a code. Information regarding the HCPCS process is available on the CMS website at *https://www.cms.gov/Medicare/;Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html.*

This proposed definition would also address prior concerns that we narrowly defined ''new'' in the context of the functional categories (that is, the drug designation process primarily addresses ''new'' drugs that fall outside of the functional categories for purposes of being newly categorized and eligible for the TDAPA). As noted in section II.B.1.f of this proposed rule, even though we are maintaining the functional categories to determine whether or not to potentially adjust or modify the ESRD PPS base rate (that is, those renal dialysis drugs and biologicals that do not fall within an existing category), we are proposing to expand the TDAPA policy based on whether the renal dialysis drug or biological is new, that is, any renal dialysis drug or biological newly approved on or after January 1, 2019.

We solicit comment on the proposed revisions to § 413.234(a), (b), and (c).

e. Basis for Expansion of the TDAPA Eligibility Criteria

In the CY 2016 ESRD PPS final rule (80 FR 69017 through 69024), we acknowledged that there are unique situations identified by the commenters during that rulemaking regarding the eligibility criteria for the TDAPA. For example, commenters stated that they believed the drug designation process was excessive, could hinder innovation, prevent new treatment options from entering the marketplace, and CMS should contemplate the cost of new drugs and biologicals that fall within the functional categories. In the following paragraphs we have summarized key concerns commenters have raised. We indicated in the CY 2016 ESRD PPS final rule that we anticipated addressing these situations in future rulemaking and stated that we planned to consider the issues of ESRD facility resource use, supporting novel therapies, and balancing the risk of including new drugs for both CMS and the dialysis facilities.

In the CY 2016 ESRD PPS final rule (80 FR 69017 through 69024), commenters seemed concerned about the cost of new drugs that fit into the functional categories, rather than the process of adding new drugs to existing categories.

In the CY 2016 ESRD PPS final rule (80 FR 69020), a drug manufacturer suggested that in order to promote access to new therapies and encourage innovation in ESRD care, the TDAPA should apply to all new drugs not just those drugs that are used to treat or manage a condition for which we have not adopted a functional category. They pointed out that the functional categories are very comprehensive and capture every known condition related to ESRD. They indicated that under the proposed approach, CMS would make no additional payment regardless of whether the drug has a novel mechanism of action, new FDA approval, or other distinguishing characteristics and argued that such distinguishing characteristics provided rationale for additional payment. The commenter believed the CMS proposal sent conflicting messages to manufacturers about the importance of developing new treatments for this underserved patient population.

An organization of home dialysis patients commented (80 FR 69022) with a similar concern, noting that the functional categories are too broad and could prevent people on dialysis from receiving needed care, and be detrimental to innovation. The commenter stated that in the future there could be a new medication to help with fluid management but patients would be shut out of ever having the option for a new fluid management therapy since there is an existing functional category for excess fluid management and therefore, these drugs are considered to be included in the base rate. Therefore, we believe the commenter meant that drug manufacturers would be less likely to develop a new fluid management drug knowing it would never qualify for additional payment under the ESRD PPS. The commenter asked that CMS provide additional payment for new drugs that fit into the functional categories in order to incentivize new medications to come to market and to ensure they have the opportunity for better care, choices and treatment.

A national dialysis patient advocacy organization explained (80 FR 69021) that if new products are immediately added to the bundle without additional payment it would curtail innovation in treatments for people on dialysis. They believed clinicians should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes, and that the proposed rule did not allow for this. The commenter explained that Kidney Disease Improving Global Outcomes (KDIGO) and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines are often updated when evidence of improved therapies on patient outcomes are made available and that this rigorous and evidence-based process is extremely important in guiding widespread

treatment decisions in nephrology. The commenter expressed concern that under the proposed rule, reimbursement and contracting arrangements could instead dictate utilization of a product before real world evidence on patient outcomes is ever generated.

The comments we received for the drug designation process in the CY 2016 ESRD PPS rulemaking (80 FR 69017 through 69024) indicated that commenters were also concerned about the cost of the new drugs and biologicals, and in particular, new drugs and biologicals that fall within the functional categories, and therefore, considered by CMS to be reflected in the ESRD PPS base rate.

A national dialysis organization strongly urged (80 FR 69017) CMS to adopt the same process for all new drugs and biologicals (as opposed to only those that do not fall within a functional category) unless they are substantially the same as drugs or biologicals currently paid for under the ESRD PPS payment rate. For new drugs or biologicals that are substantially the same as drugs or biologicals currently paid under the ESRD PPS, the organization supported incorporating them into the PPS on a case-by-case basis using notice-and-comment rulemaking and foregoing the transition period *if* it can be shown that the PPS rate is adequate to cover the cost of the drug or biological. The organization believed if the rate is inadequate to cover the cost of the new drug then the TDAPA should apply. An LDO stated that, if implemented, the proposed process could jeopardize patient access to drugs that are clinically superior to existing drugs in the same functional category. For example, the commenter stated, if a new substantially more expensive anemia management drug is released and is clinically proven to be more effective than the current standard of care under the proposed rule, the ESRD PPS base rate would remain stagnant. They continued that it is not reasonable for CMS to expect that all dialysis facilities would incur frequent and substantial losses in order to furnish the more expensive, albeit more clinically effective, drug.

A dialysis organization and a professional association asked (80 FR 69019) that CMS consider a pass-through payment, meaning Medicare payment in addition to the ESRD PPS base rate for all new drugs that are considered truly new. They recommended a rate of 106 percent of ASP, minus the portion of the ESRD PPS base rate that CMS determines is attributable to the category of drugs that corresponds to a truly new drug. An LDO stated (80 FR 69020) that defining new drugs requires special consideration of cost. They suggested a similar approach by stating that rather than comparing the cost of the new drug to the ESRD PPS base rate, we should compare it to the cost of the existing drugs in the same CMS-defined ''mode of action'' category. In such a case, a drug might qualify for payment of the TDAPA on the basis that its cost per unit or dosage exceeds a specified percentage (for example 150 percent) of the average cost per unit or dosage of the top three most common drugs in the same category (based on utilization data). This comparison would demonstrate that the amount allocated to that category in the ESRD PPS base rate is insufficient to cover the cost of the new drug.

Other commenters referred (80 FR 69020) to pathways in other payment systems that provide payment for new drugs and biologicals to account for their associated costs. For example, the Outpatient Prospective Payment System (OPPS) provides a pass-through payment and the Inpatient Prospective Payment System (IPPS) provides a new technology add-on payment. Commenters indicated (80 FR 69020) that we should decouple the TDAPA from the functional categories and provide the additional payment for all new injectable and intravenous drugs and biologicals and oral equivalents for 2 to 3 years, similar to the IPPS or the OPPS.

f. Proposed Expansion of the TDAPA Eligibility Criteria

We continue to believe that the drug designation process does not prevent ESRD facilities from furnishing available medically necessary drugs and biologicals to ESRD beneficiaries. Additionally, our position has been that payment is adequate to ESRD facilities to furnish new drugs and biologicals that fall within existing ESRD PPS functional categories. The per treatment payment amount is a patient and facility level adjusted base rate plus any applicable adjustments, such as training or outlier. Finally, the ESRD PPS includes the ESRDB market basket, which updates the PPS base rate annually for input price changes for providing renal dialysis services and accounts for price changes of the drugs and biologicals that are reflected in the ESRD PPS base rate (80 FR 69019). However, in the CY 2016 ESRD PPS final rule, we also acknowledged that the outlier policy would not fully cover the cost of furnishing a new drug (80 FR 69021) and that newer drugs may be more costly. Consequently, due to the reasons detailed in the following paragraphs, we are reconsidering our previous policy on the drug designation policy.

We recognize the unique situations identified by the commenters discussed in section II.B.1.e of this proposed rule, and how they are impacted by the eligibility criteria for the TDAPA. Concerns regarding inadequate payment for renal dialysis services and hindrance of high-value innovation, among others, are important issues that we contemplate while determining appropriate payment policies. Additionally, subsequent to the issuance of the CY 2016 ESRD PPS final rule, we continue to hear concerns that the drug designation process is restrictive in nature; and receive requests from the dialysis industry and stakeholders that we reconsider the applicability of the TDAPA.

We acknowledge that ESRD facilities have unique circumstances with regard to implementing new drugs and biologicals into their standards of care. For example, when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies into their care plans. Newly launched drugs and biologicals can be unpredictable with regard to their uptake and pricing which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We agree that this uptake period would be best supported by the TDAPA pathway because it would help facilities transition/test new drugs and biologicals in their businesses under the ESRD PPS. The TDAPA provides flexibility and targets payment for the use of new renal dialysis drugs and biologicals during the period when a product is new to the market so that we can evaluate if resource use can be aligned with payment. As explained in section II.B.1.b of this proposed rule, the ESRD PPS base rate includes dollars allocated for drugs and biologicals that fall within a functional category, but those dollars may not directly address the total resource use associated with the newly launched drugs trying to compete in the renal dialysis market.

We believe that we need to be conscious of ESRD facility resource use and the financial barriers that may be preventing uptake of innovative new drugs and biologicals that, while are already accessible to them, may be under-prescribed because the new drugs are priced higher than currently utilized drugs (as argued by commenters).

Therefore, beginning January 1, 2019, we are proposing to add § 413.234(b)(1)(i), (ii) and revise § 413.234(c) to reflect that the TDAPA, under the authority of section 1881(b)(14)(D)(iv) of the Act, would apply to all new renal dialysis injectable or intravenous products, oral equivalents, and other forms of administration drugs and biologicals, regardless of whether or not they fall within a functional category. New renal dialysis drugs and biologicals that do not fall within an existing functional category would continue to be paid under the TDAPA and the ESRD PPS base rate would be modified, if appropriate, to reflect the new functional category. We are revising § 413.234(b)(2)(ii) and § 413.234(c)(2), removing § 413.234(c)(3), and adding § 413.234(c)(2)(i) to reflect that we would continue to provide the TDAPA, collect sufficient data, and modify the ESRD PPS base rate, if appropriate, for these new drugs and biologicals that do not fall within an existing functional category.

We propose to revise § 413.234(c)(1) to reflect that for new renal dialysis drugs and biologicals that fall within a functional category, the TDAPA would apply for only 2 years. While we are not collecting claims data for purposes of analyzing utilization to result in a change to the base rate, we would still monitor renal dialysis service utilization for trends and believe that this timeframe is adequate for payment. We believe that 2 years is a sufficient timeframe for facilities to set up system modifications, and adjust business practices so that there is seamless access to these new drugs within the ESRD PPS base rate. In addition, when we implement policy changes whereby facilities need to adjust their system modifications or protocols, we have provided a transition period. We believe that this 2-year timeframe is similar in that facilities are making changes to their systems and care plan to incorporate the new renal dialysis drugs and biologicals into their standards of care and this could be supported by a transition period. Also, the TDAPA for 2 years would address the stakeholders concerns regarding additional payment to account for higher cost of more innovative drugs that perhaps may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, this transitional payment would give the new renal dialysis drugs and biologicals a foothold in the market so that when the timeframe is complete, they are able to compete with the existing drugs and biologicals under the outlier policy, if applicable. Meaning, once the timeframe is complete, drugs would then qualify as outlier services, if applicable, and the facility would no longer receive the TDAPA for any one particular drug. Instead, in the outlier policy space, there is a level playing field where drugs could gain market share by offering the best practicable combination of price and quality. We believe that the proposed timeframe is long enough to be meaningful but not too long as to improperly incentivize high cost items without more value, for example, substitutions of those drugs that already exist in the functional category.

We note that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary cost sharing, since we have not previously provided the TDAPA for new renal dialysis drugs and biologicals in the past. It is our understanding that there are new drugs and biologicals in the pipelines, for example, we are aware that there are new drugs that would fall within the anemia management, bone and mineral, and pain management categories. We would continue to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biologicals that qualify. We would address any concerns through future refinements to the TDAPA policy.

We are also proposing that when a new renal dialysis drug or biological falls within an existing functional category at the end of the TDAPA period we would not modify the ESRD PPS base rate, but at the end of the 2 years, as consistent with the existing outlier policy, the drug would be eligible for outlier payment. However, as discussed in section II.B.1.h of this proposed rule, if the new renal dialysis drug or biological is considered to be a composite rate drug, it would not be eligible for an outlier payment. The intent of the TDAPA for these drugs is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new drug. We do not believe that it would be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biologicals that fall within existing functional categories and that doing such would be in conflict with the fundamental principles of a PPS. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's cost which creates an incentive for cost control. It is not the intent of a PPS to add dollars to the base whenever something new is made available. We believe this proposal, that is, no modification to the base rate at the end of the TDAPA period for new renal dialysis drugs and biologicals that fall within an existing functional category would maintain the overall goal of a bundled PPS, that is, the limitation of applying the TDAPA would not undermine the bundle since there is no permanent adjustment to the base rate. This proposal would also strike a balance of maintaining the existing functional category scheme of the drug designation process and not adding dollars to the ESRD PPS base rate when the base rate may already reflect costs associated with such services, while still promoting high-value innovation and allowing facilities to adjust or factor in new drugs through a short-term transitional payment. We are proposing to add § 413.234(c)(1)(i) to reflect that when a new renal dialysis drug or biological falls within an existing functional category at the end of the TDAPA period, we would not modify the ESRD PPS base rate. We solicit comment on this proposal.

We are proposing to operationalize this proposed policy no later than January 1, 2020. This deadline would provide us with the appropriate time to prepare the necessary changes to our claims processing systems.

We solicit comment on the proposal to revise § 413.234(c) and (c)(1) to reflect that the TDAPA would apply for all new renal dialysis drugs and biologicals regardless of whether they fall within a functional category. Then, for new renal dialysis drug or biological that falls within an existing functional category, that payment would apply for 2 years and there would be no modification to the ESRD PPS base rate. We are also soliciting comment on the appropriateness of the 2-year timeframe for the TDAPA for new renal dialysis drugs and biologicals that fall within existing functional categories.

g. Proposed Basis of Payment for the TDAPA

Currently, under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act, including 106 percent of ASP (ASP+6). If we adopt the proposals discussed in section II.B.1.f of this proposed rule using the same pricing methodologies, Medicare expenditures would increase, which would result in increases of cost sharing for ESRD beneficiaries, since we have not previously provided the TDAPA for all new renal dialysis drugs and biologicals in the past.

The TDAPA is a payment adjustment under the ESRD PPS and is not intended to be a mechanism for payment for new drugs and biologicals under Medicare Part B, and under section 1881(b)(14)(D)(iv) of the Act, we believe it may not be appropriate to base the TDAPA strictly on section 1847A of the Act methodologies. For this proposed rule, we considered options for basing payment under the TDAPA, for example, maintaining the policy as is and facility cost of acquiring drugs and biologicals. We found that the while ASP could encourage certain unintended consequences (discussed below), it continues to be the best data available since it is commonly used to facilitate Medicare payment across care settings and, as described in section II.B.1.c, is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions.

Further, since the implementation of section 1847A of the Act, stakeholders and executive policy advisors have analyzed this section of the statute and issued their respective critiques on the purpose of the ASP add-on percentage. On March 8, 2016, the Assistant Secretary for Planning and Evaluation (ASPE) issued an Issue Brief titled, ''Medicare Part B Drugs: Pricing and Incentives'' (*https://aspe.hhs.gov/system/files/pdf/;187581/PartBDrug.pdf*). In this brief ASPE touches on several concerns they have about the ASP methodology. Two of those concerns regard the economic incentives of cost and value. ASPE noted that the ASP methodology for Part B drugs falls short of providing value based incentives in several ways. Specifically, they noted physicians can often choose between several similar drugs for treating a patient and although the current system may encourage providers and suppliers to pursue the lowest price for drugs that are multiple source, payment based on drug specific ASP provides little incentive to make choices among the therapeutic options with an eye towards value and choose among the lowest price among all drugs available to effectively treat a patient. Rationale for the 6 percent add-on has been to cover administrative and overhead costs, but such costs are not proportional to the price of the drug. The fixed 6 percent of ASP provides a larger ''add-on'' for higher priced drugs than for lower priced drugs, resulting in increased profit margins for the physicians' office and hospitals creating a perverse incentive to choose the high priced drugs as opposed to lower priced alternatives of similar effectiveness.

In MedPAC's June 2015 Report to Congress (*http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*), MedPAC provides discussion around the meaning of the 6 percent that is added to the ASP and provides their opinion on its purpose. In their report, they state ''There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent is intended to cover drug storage and handling costs. Others contend that the 6 percent is intended to maintain access to drugs for smaller practices and other purchasers who may pay above average prices for the drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (for example, prompt-pay discounts). Another rationale for the percentage add-on may be to provide protection for providers when price increases occur and the payment rate has not yet caught up.''

Finally, with regard to acquisition costs in a 2006 Report to Congress titled, ''Sales of Drugs and Biologicals to Large Volume Producers (*https://www.cms.gov/Research-Statistics-Data-and-Systems/;Statistics-Trends-and-Reports/Reports/Downloads/LVP_RTC_2_09_06.pdf*), the Secretary was tasked to submit a Report to Congress (RTC) to include recommendations as to whether sales to large volume purchasers should be excluded from the computation of manufacturer's ASP. The contractor made extensive efforts to collect and analyze data regarding large volume drug purchasers. They were unable to obtain data on ASP by type of purchaser from the drug manufacturers, and were unable to determine net acquisition costs. The sensitive and proprietary nature of prescription drug pricing data made it extremely difficult to obtain the data necessary for the report. Given that ASP was designed to broadly reflect market prices without data on net acquisition cost, it is not possible to accurately analyze the impact of large volume purchasers on overall ASP. In 2018, we remain unable to obtain contractual information regarding drug pricing and ESRD PPS, which is especially pertinent since the dialysis stage is dominated by two large dialysis organizations who administer drugs and biologicals to the majority of ESRD beneficiaries.

To balance the price controls inherent in any PPS we believe that we need to take all of these issues into consideration to revise the basis for TDAPA payment. We are, and will continue to be, conscious of ESRD facility resource use and recognize the financial barriers that may be preventing uptake of innovative new drugs and biologicals. Therefore, we are proposing to revise § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we would base the TDAPA payments on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6).

This proposal applies to new renal dialysis drugs and biologicals that fall within an existing functional category and to those that do not fall within an existing functional category. We believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biologicals that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biologicals that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biologicals. We note that there is no clear statement from Congress as to why the payment allowance is required to be 106 percent of ASP (ASP+6) as opposed to any other value from 101 to 105 percent, and, as MedPAC discussed in their June 2015 report, there is no consensus amongst stakeholders.

We further believe that moving from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0 for all new renal dialysis drugs and biologicals regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary coinsurance) and stakeholder concerns discussed in section II.B.1.e of this proposed rule. That is, we propose to provide the TDAPA for new drugs that are within an existing functional category, which is an expansion from the existing policy. This proposal would also aim to promote innovation and bring more high-value drugs to market. This proposal would further address concerns about incentivizing use of high cost drugs in ESRD facilities, also discussed in section II.B.1.e of this proposed rule. We

solicit comment on the proposal to revise § 413.234(c) to reflect that we would base the TDAPA payments on ASP+0. While we propose to change the basis of payment for the TDAPA from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0, we are also soliciting comment on other add-on percentages to the ASP amount, that is, ASP+1 to 6 percent for commenters to explain why it may be appropriate to have a higher percentage.

There are times when the ASP is not available. For example, when a new drug or biological is brought to the market, sales data is not sufficiently available for the manufacturer to compute an ASP. Therefore, when the ASP is not available, we propose that the TDAPA payment would be based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the TDAPA payment would be based on the drug manufacturer's invoice. We solicit comment on this proposal.

We note that this proposal to use ASP+0 as the basis for the TDAPA payments, if adopted, would apply prospectively to new drugs and biologicals as of January 1, 2019. Currently, calcimimetics are eligible for the TDAPA and payment for both the injectable and oral versions are based on pricing methodologies under section 1847A of the Act. This proposal would not affect calcimimetics, which would continue to be eligible for the TDAPA payment based on ASP+6.

h. Drug Designation Process for Composite Rate Drugs and Biologicals

In the CY 2016 ESRD PPS final rule, we did not discuss composite rate drugs and biologicals explicitly in context of the drug designation process. Composite rate services are discussed in the CY 2011 ESRD PPS final rule (75 FR 49036, 49078 through 49079) and are identified as renal dialysis services in § 413.171 and under section 1847(b)(14)(B) of the Act. Prior to the implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysis treatments were considered composite rate drugs and not billed separately. Composite rate drug and biological policies are discussed in Pub. 100–02, chapter 11, section 20.3.F (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf*). This manual lists the drugs and fluids considered in the composite rate as heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, and verapamil. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the ESRD PPS.

We used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate. These are identified on Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as ''Composite Rate Services''. In addition, we note that under § 413.237, composite rate drugs and biologicals are not permitted to be considered for an outlier payment. The outlier policy is discussed in section II.B.3.c of this proposed rule.

Composite rate drugs and biologicals were also grouped into functional categories during the drug categorization for the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053). For example, heparin is a composite rate drug and falls within the Access Management category. However, these functional categories exclude certain composite rate items given that certain drugs and biologicals formerly paid for under the composite rate were those that were routinely given during the time of the patient's dialysis and not always specifically for the treatment of their ESRD. For example, an antihypertensive composite rate drug that falls within the Cardiac Management category, which is not an ESRD PPS functional category, is not considered to be furnished for the treatment of ESRD and therefore, not included under the ESRD PPS.

In light of our proposal to expand the drug designation process and the TDAPA, we also propose, under the authority of section 1881(b)(14)(D)(iv) of the Act, that it extend to composite rate drugs and biologicals that are furnished for the treatment of ESRD. Specifically, beginning January 1, 2019, we propose that if a new renal dialysis drug or biological as defined in the proposed revision at § 413.234(a) is considered to be a composite rate drug or biological and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. We note that composite rate drugs and biologicals that are not considered to be furnished for the treatment of ESRD, and therefore, are not included in the ESRD PPS, would not be eligible for the TDAPA, for example, antihypertensives. We believe that the same unique consideration for innovation and cost exists for drugs that are considered composite rate drugs. That is, the ESRD PPS base rate dollars allocated for these types of drugs may not directly address the costs associated with drugs in this category when they are newly launched and are finding their place in the market. Accordingly, we propose that the expanded drug designation process and the TDAPA policy we proposed in section II.B.1.f of this proposed rule, including the proposed changes to § 413.234, would be applicable to composite rate drugs, with one exception. Under our proposal, new composite rate drugs would not be subject to outlier payments following the period that the TDAPA applies, since we are not proposing to change the current outlier policy under § 413.237, which does not apply to composite rate drugs. We are, however, soliciting comments on whether we should consider applying our outlier policy to composite rate drugs in the future (see section II.B.3.c of this proposed rule). We would continue to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biologicals that qualify. We would address any concerns through future refinements to the TDAPA policy.

We solicit comment on the proposal to recognize composite rate drugs and biologicals in the same manner as drugs that were formerly separately paid under Part B when furnished for the treatment of ESRD for purposes of the proposed revisions to the drug designation process and eligibility for the TDAPA.

2. Low-Volume Payment Adjustment (LVPA) Revision

a. Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS includes a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities furnishing such services. We have established a low-volume payment adjustment (LVPA) factor of 23.9 percent for ESRD facilities that meet the definition of a low-volume facility. Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question.

For purposes of determining eligibility for the LVPA, ''treatments'' means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare as well as ESRD and non-ESRD). For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 HD treatments. As noted, we base eligibility on the 3 years preceding the payment year and those years are based on cost reporting periods. Specifically, under § 413.232(g), the ESRD facility's cost reports for the periods ending in the 3 years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified § 413.232 and qualifies as a low-volume ESRD facility. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions. This timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, CMS Pub. 100–02, Chapter 11, section 60.B.1.

b. Revisions to the LVPA Requirements and Regulations

We have heard from stakeholders that low-volume facilities rely on the low-volume adjustment and loss of the adjustment could result in beneficiary access issues. Specifically, stakeholders expressed concern that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility in certain circumstances. For example, in the CY 2017 ESRD PPS final rule (81 FR 77863), a commenter suggested refinements to the definition of a low-volume facility to address the rare change of ownership (CHOW) instance wherein the new owner accepts the Medicare agreement but the ownership change results in a new provider number because of a facility's type reclassification. The commenter explained that in this example, due to the issuance of a new Medicare provider billing number or provider transaction access number (PTAN) when the facility's type is reclassified, this facility would be deemed ineligible for the LVPA since our policy requires new Medicare provider billing numbers qualify for the LVPA, which takes 3 years. We also discovered that facilities that change their fiscal year without going through a CHOW become ineligible for the adjustment. Finally, stakeholders also communicated that the strict enforcement of the attestation deadline without exception should be reevaluated since missing the deadline results in the facility losing the LVPA and their payments are significantly reduced. Thus, in order to be responsive to stakeholders and increase flexibility with regard to eligibility for the LVPA, we are proposing to make changes to the LVPA regulation at § 413.232.

The first proposed revision concerns the assignment of a PTAN when a facility undergoes a CHOW as described in 42 CFR 489.18. A facility is ineligible under § 413.232(b)(2) and (g)(2) for the LVPA for 3 years if it goes through a CHOW that results in a new PTAN. In response to a comment we received during the CY 2011 ESRD PPS rulemaking (75 FR 49123), we explained that we believe that a 3-year waiting period serves as a safeguard against facilities establishing new facilities that are purposefully small. We also explained that we structured our analysis of the ESRD PPS by looking across data for 3 years as we believe that the 3-year timeframe provided us with a sufficient span of time to view consistency in business operations.

However, as we mentioned above, we have heard from stakeholders that this policy unfairly impacts facilities that undergo a CHOW that results in a change in facility type (for example, the facility type changes from hospital-based to freestanding). Under this scenario, as discussed in the Medicare State Operations Manual, Pub. 100–07, Chapter 3, Section 3210.4C (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c03.pdf*) and the Medicare Program Integrity Manual, Pub. 100–08, Chapter 15, Section 15.7.7.1 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15.pdf*), CMS requires the issuance of a new CMS Certification Number (CCN) and provider agreement, which may lead to the issuance of a new PTAN, even if the new owner has accepted assignment of the existing Medicare provider agreement, that is, the new owner accepts the previous owner's assets and liabilities.

We agree with the stakeholders that the language in the regulation regarding PTAN status could restrict LVPA eligibility to an otherwise qualified ESRD facility from receiving the adjustment for 3 years, until the new PTAN qualifies for the adjustment. We recognize that there are technicalities regarding the assignment of a PTAN that could cause substantive impacts with eligibility for the LVPA that were not contemplated at the time the regulation was established. The intent of the LVPA has always been that if an ESRD facility undergoes a CHOW wherein the new owner accepts assignment of the existing Medicare provider agreement that they should continue to be eligible for the LVPA since this indicates a consistency in business operations.

We are proposing to expand the definition of a low-volume facility in § 413.232(b)(2) to include CHOWs where the new owner accepts assignment of the existing Medicare provider agreement and a new PTAN is issued due to a change in facility type. This proposal does not extend to CHOWs where a new PTAN is issued for any other reason. We solicit comment on the proposal to revise the language at § 413.232(b)(2) to reflect that ESRD facilities can meet the definition of a low-volume facility when they have a CHOW that results in a new PTAN due to a change in facility type but accepts assignment of the existing Medicare provider agreement. We are also proposing to amend § 413.232(g)(2), which governs the determination of LVPA eligibility, to recognize the proposed expansion of the low-volume facility definition to allow for PTAN changes when the facility type changes as a result of CHOW. We solicit comment on this proposal.

We are also proposing to allow for an extraordinary circumstance exception to the November 1 attestation deadline under § 413.232(e). We agree with the stakeholders that there could be unforeseeable factors that contribute to a delay in the submission of the attestation and we would not want to prevent an otherwise qualified ESRD facility from receiving the adjustment. For example, while a failure to timely submit the attestation because of poor communication between a facility and its respective MAC, or because a facility forgets to send the attestation to the MAC, would not constitute extraordinary circumstances; a natural disaster could, because such an event is unforeseeable and extraordinary, which may understandably delay the timely submission of the attestation. We expect

extraordinary exceptions to be rare and the determination of acceptability would be made on a case-by-case basis. We have heard from stakeholders that they have lost eligibility for the LVPA due to extraordinary circumstances, such as natural disasters, that prevented them from submitting their attestation by the deadline. In those types of instances, we believe an exception to the attestation deadline could be warranted. Therefore, we are proposing to add a clause in § 413.232(e) to recognize an exception to the filing deadline for extraordinary circumstances. In order to request an extraordinary circumstance exception, we also propose that the facility would need to submit a narrative explaining the rationale for the exception to their MAC. We would evaluate and review the narrative to determine if an exception is justified, and such a determination would be final, with no appeal. We solicit comment on the proposal to revise the language at § 413.232(e) to reflect that CMS would allow an exception to the attestation deadline of November 1 for extraordinary circumstances, if determined appropriate.

In addition, we are also proposing to allow ESRD facilities that change their fiscal year-end for cost reporting purposes outside of a CHOW to qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. Under § 413.24(f)(3), facilities are able to change their cost reporting period when they request a change in writing from their MAC and meet specific criteria for approval. However, the current LVPA regulation at § 413.232(g)(2)(ii) does not technically address requirements for changing cost reporting periods except as a result of a CHOW, which has prohibited facilities from receiving the LVPA if they make a business decision to adjust their cost reporting period, which could interfere with the normal course of business. We recognize that there are business decisions an ESRD facility could make with regard to cost reporting periods that could substantively impact eligibility for the LVPA that we did not contemplate at the time the regulation was adopted. Specifically, there could be reasons why a cost report does not span 12-consecutive months. We did not intend for an ESRD facility to lose their LVPA eligibility simply because they made a decision to change their cost reporting period. The requirement that cost reports span 12-consecutive months was to bring a measure of consistent business operations.

We are proposing to add a new paragraph (3) to § 413.232(g) to provide direction for MACs in verifying the number of treatments when a change in a cost reporting period is approved. When this occurs, we propose that MACs would combine the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period or combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period. This proposal does not impact or change requirements for reporting, as established by the MACs, or those set forth in § 413.24(f)(3). We solicit comment on the proposal to add proposed § 413.232(g)(3) to change the information and cost report timeframes MACs would review to determine LVPA eligibility. This would apply to ESRD facilities that change their cost reporting year for purposes outside of a CHOW to qualify for the LVPA, provided they otherwise meet the LVPA eligibility criteria for the purposes of allowing the ESRD facility to continue to receive the adjustment.

Finally, we are proposing two additional changes to correct and further clarify the LVPA regulation. The first would correct a cross-reference in § 413.232(b) by changing ''paragraph (h)'' to ''paragraph (g)''. This error is the result of prior changes we made to the regulation when we deleted other paragraphs, but did not update the reference accordingly. The second proposed revision, which we are making to § 413.232(c)(2), would clarify that the reference to miles, are road miles. CMS recognizes that the current designation of miles under the regulation may not be specific enough and could cause confusion, and we have issued guidance (Medicare Benefit Policy Manual, Pub. L. 100–02, Chapter 11, Section 60) addressing road miles. Accordingly, we are proposing clarifying edits to § 413.232(c)(2).

3. Proposed CY 2019 ESRD PPS Update

a. ESRD Bundled (ESRDB) Market Basket and Labor-Related Share

i. Proposed Rebasing of the ESRDB Market Basket

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162) and subsequently revised and rebased the ESRDB input price index in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). Effective for CY 2019, we are proposing to rebase the ESRDB market basket to a base year of CY 2016.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2016 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy''. In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time.

Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services purchased to provide ESRD services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an ESRD facility hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the ESRD facility, but would not be factored into the price change measured by a fixed-weight ESRD market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

We are proposing to use CY 2016 as the base year for the proposed rebased ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2016 (that is, the average index level for CY 2016 is equal to 100). The major source data for the proposed ESRDB market basket is the 2016 Medicare cost reports (MCRs) (Form CMS–265–11), supplemented with 2012 data from the United States (U.S.) Census Bureau's Services Annual Survey (SAS) inflated to 2016 levels. The 2012 SAS data is the most recent year of detailed expense data published by the Census Bureau for North American International Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We also are proposing to use May 2016 Bureau of Labor Statistics (BLS) Occupational Employment Statistics data to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends. We provide more detail on our methodology below.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in this exercise, we are proposing to move the base year cost structure from CY 2012 to CY 2016) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and/or price proxies used in the input price index. For CY 2019, we are proposing to rebase the ESRD market basket to reflect the 2016 cost structure of ESRD facilities. We are not proposing to revise the index; that is, we are not proposing to make any changes to the cost categories or price proxies used in the index.

We selected CY 2016 as the new base year because 2016 is the most recent year for which relatively complete MCR data are available. In developing the proposed market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11) for 2016 for each freestanding ESRD facility that reported expenses and payments. The 2016 MCRs are those ESRD facilities whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. Of the 2016 MCRs, approximately 88 percent of freestanding ESRD facilities had a begin date on January 1, 2016, approximately 6 percent had a begin date prior to January 1, 2016, and approximately 6 percent had a begin date after January 1, 2016. Using this methodology allowed our sample to include ESRDs with varying cost report years including, but not limited to, the federal fiscal or CY.

We propose to maintain our policy of using data from freestanding ESRD facilities (which account for over 90 percent of total ESRD facilities) because freestanding ESRD data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for a hospital-based ESRD reflect the allocation of overhead from the entire institution.

We developed cost category weights for the proposed 2016-based ESRDB market basket in two stages. First, we derived base year cost weights for nine major categories (Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Housekeeping and Operations, Administrative and General, Capital-Related Building and Fixtures, and Capital-Related Machinery) from the ESRD MCRs. Second, we are proposing to divide the Administrative and General cost category into further detail using 2012 U.S. Census Bureau Services Annual Survey (SAS) data for the industry Kidney Dialysis Centers NAICS 621492 inflated to 2016 levels. We apply the estimated 2016 distributions from the SAS data to the 2016 Administrative and General cost weight to yield the more detailed 2016 cost weights in the proposed market basket. This is similar to the methodology we used to break the Administrative and General costs into more detail for the 2012-based ESRDB market basket (79 FR 40217 through 40221). The only difference is that for this proposed rebasing because SAS data is not available after 2012 we inflated the 2012 expense levels to 2016 dollars using appropriate price proxies and applied this expense distribution to the Administrative and General cost weight for 2016.

We are proposing to include a total of 20 detailed cost categories for the proposed 2016-based ESRDB market basket, which is the same number of cost categories as the 2012-based ESRDB market basket. We are proposing to continue to assume that 87 percent of Professional Fees and 46 percent of capital costs are labor-related costs and would be included in the proposed labor-related share. A more thorough discussion of our proposals is provided below.

a. Cost Category Weights

Using Worksheets A and B from the 2016 MCRs, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Housekeeping and Operations, Administrative and General, Capital-Related Building and Equipment, and Capital-Related Machinery. Edits were applied to include only cost reports that had total costs greater than zero. Total costs as reported on the MCR include those costs reimbursable under the ESRD bundled payment system. For example, we excluded expenses related to vaccine costs from total expenditures since these are not reimbursable under the ESRD bundled payment.

In order to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The proposed data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 5,700 independent ESRD facilities' cost reports from an available pool of 6,410 cost reports.

Table 2 presents the proposed 2016-based ESRDB and 2012-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 2—PROPOSED 2016-BASED ESRDB MARKET BASKET MAJOR COST WEIGHTS DERIVED FROM THE MEDICARE COST REPORT DATA

Cost category	Proposed 2016-based ESRDB market basket (percent)	2012-based ESRDB market basket (percent)
Wages and Salaries	32.6	31.8
Employee Benefits	7.0	6.6
Pharmaceuticals	12.4	16.5
Supplies	10.4	10.1
Lab Services	2.2	1.5
Housekeeping and Operations	3.9	3.8
Administrative and General	18.4	17.4
Capital-related Building and Fixed Equipment	9.2	8.4
Capital-related Machinery	3.8	3.9

Note: Totals may not sum to 100.0 percent due to rounding.

We are proposing to disaggregate certain major cost categories developed from the MCRs into more detail to more accurately reflect ESRD facility costs. Those categories include: Benefits, Professional fees, Telephone, Utilities, and All Other Goods and Services. We describe below how the initially computed categories and weights from the cost reports were modified to yield the proposed 2016 ESRDB market basket expenditure categories and weights presented in this proposed rule.

Wages and Salaries

The proposed Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 2016 was derived from Worksheet B, column 5, lines 8 through 17 of the MCR. Non-direct patient care wages and salaries includes all other wages and salaries costs for non-health workers and physicians, which we are proposing to derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the MCR. The estimated ratios were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct cost centers: 'Operations and Maintenance' combined with 'Machinery & Rental & Maintenance' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W) Benefits for Direct Patient Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Pharmaceuticals (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total costs for each corresponding reimbursable costs center totals as reported on Worksheet B. The Worksheet B totals were based on the sum of reimbursable costs reported on lines 8 through 17. For example, the salary percentage for Supplies (as measured by line 9 on Worksheet A) was applied to the total expenses for the Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8 through 17). This provided us with an estimate of Non-Direct Patient Care Wages and Salaries.

Step 3: The estimated Wages and Salaries for each of the cost centers on Worksheet B derived in step 2 were subsequently summed and added to the direct patient care wages and salaries costs.

Step 4: The estimated non-direct patient care wages and salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

Using this methodology, we derive a proposed Wages and Salaries cost weight of 32.6 percent, reflecting an estimated direct patient care wages and salaries cost weight of 25.1 percent and non-direct patient care wages and salaries cost weight of 7.5 percent, as seen in Table 3.

The final adjustment made to this category is to include Contract Labor costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid double counting of these expenses, we propose to remove the estimated cost weight for the contract labor costs from the Administrative and General category (where we believe the majority of the contract labor costs would be reported) to the Wages and Salaries category. We are proposing to use data from the SAS (2012 data inflated to 2016), which reported 2.3 percent of total expenses were spent on contract labor costs. We allocated 80 percent of that contract labor cost weight to Wages and Salaries. At the same time, we subtracted that same amount from Administrative and General, where the majority of contract labor expenses would likely be reported on the MCR. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2016 MCR data. This is the same method that was used to allocate contract labor costs to the Wages and Salaries cost category for the 2012-based ESRDB market basket.

The resulting proposed cost weight for Wages and Salaries increases to 34.5 percent when contract labor wages are added. The calculation of the proposed Wages and Salaries cost weight for the 2016-based ESRDB market basket is shown in Table 3 along with the similar calculation for the 2012-based ESRDB market basket.

TABLE 3—PROPOSED 2016 AND 2012 ESRD WAGES AND SALARIES COST WEIGHT DETERMINATION

Components	Proposed 2016 cost weight (percent)	2012 cost weight (percent)	Source
Wages and Salaries Direct Patient Care	25.1	23.2	MCR.
Wages and Salaries Non-direct Patient Care	7.5	8.6	MCR.
Contract Labor (Wages)	1.9	1.8	80% of SAS Contract Labor weight.
Total Wages and Salaries	34.5	33.7	

Employee Benefits

The Employee Benefits cost weight was derived from the MCR data for direct patient care and supplemented with data from the SAS (2012 data inflated to 2016) to account for non-direct patient care Employee Benefits. The MCR data only reflects Employee Benefit costs associated with health and wellness; that is, it does not reflect retirement benefits.

In order to reflect the benefits related to non-direct patient care for employee health and wellness, we estimated the impact on the benefit weight using SAS. Unlike the MCR, data from the SAS benefits share includes expenses related to the retirement and pension benefits. In order to be consistent with the cost report definitions we do not want to include the costs associated with retirement and pension benefits in the cost share weights. These costs are relatively small compared to the costs for the health-related benefits, accounting for only 2.7 percent of the total benefits costs as reported on the SAS. Incorporating the SAS data produced an Employee Benefits (both direct patient care and non-direct patient care) weight that was 1.6 percentage points higher (8.6 vs. 7.0) than the Employee Benefits weight for direct patient care calculated directly from the MCR. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.6 percentage points for Non-Direct Patient Care Employee Benefits from the Administrative and General cost category (where we believe the majority of the contract labor costs would be reported).

The final adjustment made to this category is to include contract labor benefit costs. Once again, these costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCR data. Identical to our methodology above for allocating Contract Labor Costs to Wages and Benefits, we applied 20 percent of total Contract Labor Costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The 20 percent figure was determined by taking benefits as a percentage of total compensation (excluding contract labor) from the 2016 MCR data. The resulting cost weight for Employee Benefits increases to 9.1 percent when contract labor benefits are added. This is the same method that was used to allocate contract labor costs to the Benefits cost category for the 2012-based ESRDB market basket.

The Table 4 compares the 2012-based Benefits cost share derivation as detailed in the CY 2015 ESRD proposed rule (79 FR 40218) to the proposed 2016-based Benefits cost share derivation.

TABLE 4—PROPOSED 2016 AND 2012 ESRD EMPLOYEE BENEFITS COST WEIGHT DETERMINATION

Components	Proposed 2016 cost weight (percent)	2012 cost weight (percent)	Source
Employee Benefits Direct Patient Care	7.0	6.6	MCR.
Employee Benefits Non-direct Patient Care	1.6	1.8	SAS.
Contract Labor (Benefits)	0.5	0.5	20% of SAS Contract Labor weight.
Total Employee Benefits	9.1	8.8	

Pharmaceuticals

The proposed 2016-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We calculated a Pharmaceutical cost weight from the following cost centers on Worksheet B, the sum of lines 8 through 17, for the following columns: 11 ''Drugs Included in Composite Rate''; 12 ''Erythropoiesis stimulating agents (ESAs)''; 13 ''ESRD-Related Drugs''. We also added the drug expenses reported on line 5 column 10 ''Non-ESRD related drugs''. The Non-ESRD related drugs would include drugs and biologicals administered during dialysis for non-ESRD related conditions as well as oral-only drugs. Since these are costs to the facility for providing ESRD treatment to the patient, we propose to continue to include them in the Pharmaceutical cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these vaccines are not reimbursable under the ESRD PPS, we exclude them from the proposed 2016-based ESRDB market basket.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with the applicable pharmaceutical cost centers referenced above. This resulted in a proposed ESRDB market basket weight for Pharmaceuticals of 12.4 percent. ESA expenditures accounted for 10.0 percentage points of the proposed Pharmaceuticals cost weight, and All

Other Drugs accounted for the remaining 2.4 percentage points.

The Pharmaceutical cost weight decreased 4.1 percentage point from the 2012-based ESRD market basket to the proposed 2016-based ESRD market basket (16.5 percent to 12.4 percent). Most providers experienced a decrease in their Pharmaceutical cost weight since 2012. One provider in particular, a major dialysis provider, experienced a significant pharmaceutical cost weight decline in 2016. This provider's decline has an effect on the overall Pharmaceutical cost weight in the proposed 2016-based ESRDB market basket. We wish to note that the provider's decline in the pharmaceutical cost weight was found across the board in all states where the provider has facilities. Given this, we are proposing to include this provider's decline in our market basket results treating it as a 'real' change in relative pharmaceutical costs. We are not proposing to use an alternative methodology, such as averaging cost weights from multiple years, as proposed for Lab Services.

Supplies

We calculated the Supplies cost weight using the costs reported in the Supplies cost center (Worksheet B, line 5 and the sum of lines 8 through 17, column 7) of the MCR. To avoid double-counting, the Supplies costs were reduced to exclude the estimated share of Non-Direct patient care Wages and Salaries associated with this cost center. The resulting proposed 2016-based ESRDB market basket weight for Supplies is 10.4 percent, about the same as the weight for the 2012-based ESRDB market basket.

Lab Services

We calculated the Lab Services cost weight using the costs reported in the Laboratory cost center (Worksheet B, line 5 and the sum of line 8 through 17, column 8) of the MCR. To avoid double-counting, the Lab Services costs were reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The proposed 2016-based ESRDB market basket weight for Lab Services is estimated at 2.2 percent.

The 2016 Lab Services expenses reported for a main chain provider were significantly lower than those reported in the 3 years prior (2013–2015) and lower than the 2016 Lab Services weight for all other providers. We believe the lower costs were based on a correction to the way that this chain is billing for these services, an assumption that is supported by the findings of a January 2016 Health and Human Services Office of the Inspector General (OIG) Report.[2] Because the recent reported costs from this chain reflect these unique circumstances, we propose to take a 2-year average of Lab Services costs for 2015 and 2016 for this chain in order to smooth out the year-to-year volatility. This approach results in a Lab cost weight for this chain that is higher than it was in 2012, which is then added to the 2016 Lab Services costs for all other providers, where the cost weight was similar in 2012 and 2016. As a result, the overall Lab Services cost weight increased 0.7 percentage points from the 2012-based ESRDB market basket to the proposed 2016-based ESRD market basket.

Housekeeping and Operations

We calculated the Housekeeping and Operations cost weight using the costs reported on Worksheet A, lines 3 and 4, column 8, of the MCR. To avoid double-counting, the weight for the Housekeeping and Operations category was reduced to exclude the estimated share of Non-Direct Patient Care Waged and Salaries associated with this cost center. These costs were divided by total costs to derive a proposed 2016-based ESRDB market basket weight for Housekeeping and Operations of 3.9 percent.

Capital

We developed a proposed market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because Housekeeping and Operations and Maintenance costs are included in the Worksheet B cost center for Capital-Related costs (Worksheet B, column 2), we excluded the costs for these two categories and developed a separate expenditure category for Housekeeping and Operations, as detailed above. Similar to the methodology used for other market basket cost categories with a salaries component, we computed a share for non-direct patient care Wages and Salaries and Benefits associated with the Capital-related cost centers. We used Worksheet B to develop two capital-related cost categories: (1) Buildings and Fixtures (Worksheet B, the sum of lines 8 through 17, column 2 less housekeeping & operations as derived from expenses reported on Worksheet A (see above)), and (2) Machinery (Worksheet B, the sum of lines 8 through 17, column 4). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Equipment could move differently than those associated with Machinery, we continue to believe that two capital-related cost categories are appropriate. The resulting proposed 2016-based ESRDB market basket weights for Capital-related Buildings and Fixtures and Capital-related Machinery are 9.2 and 3.8 percent, respectively.

Administrative and General

We computed the proportion of total Administrative and General expenditures using the Administrative and General cost center data from Worksheet B, the sum of lines 8 through 17, (column 9) of the MCRs. Additionally, we remove contract labor from this cost category and apportion these costs to the Wages and Salaries and Employee Benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude Wages and Salaries and Benefits associated with the Administrative and General cost center for Non-direct Patient Care as estimated from the SAS data. The resulting Administrative and General cost weight is 14.5 percent.

We are proposing to further disaggregate the Administrative and General cost weight to derive detailed cost weights for Electricity, Natural Gas, Water and Sewerage, Telephone, Professional Fees, and All Other Goods and Services. These detailed cost weights are derived by inflating the detailed 2012 SAS data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 SAS data. We repeat this practice for each year to 2016. We then calculate the cost shares that each cost category represents of the 2012 data inflated to 2016. These resulting 2016 cost shares were applied to the Administrative and General cost weight derived from the MCR (net of contract labor and additional benefits) to obtain the detailed cost weights for the proposed 2016-based ESRD market basket. This method is similar to the method used for the 2012-based ESRDB market basket.

Table 5 lists all of the cost categories and cost weights in the proposed 2016-

[2] Review of Medicare Payments for Laboratory Tests Billed with an AY Modifier by Total Renal Laboratories, Inc.; *https://oig.hhs.gov/oas/reports/region1/11400505.pdf.*

based ESRDB market basket compared to the 2012-based ESRDB market basket.

TABLE 5—COMPARISON OF THE PROPOSED 2016-BASED AND THE 2012-BASED ESRDB MARKET BASKET COST CATEGORIES AND WEIGHTS

Proposed 2016 cost category	Proposed 2016 cost weights (percent)	2012 cost weights (percent)
Total	100.0	100.0
Compensation	43.6	42.5
Wages and Salaries	34.5	33.7
Employee Benefits	9.1	8.8
Utilities	2.0	1.8
Electricity	1.1	1.0
Natural Gas	0.1	0.1
Water and Sewerage	0.8	0.8
Medical Materials and Supplies	24.9	28.1
Pharmaceuticals	12.4	16.5
ESAs	10.0	12.9
Other Drugs (except ESAs)	2.4	3.6
Supplies	10.4	10.1
Lab Services	2.2	1.5
All Other Goods and Services	16.4	15.3
Telephone & Internet Services	0.5	0.5
Housekeeping and Operations	3.9	3.8
Professional Fees	0.7	0.6
All Other Goods and Services	11.3	10.4
Capital Costs	13.0	12.2
Capital Related-Building and Fixtures	9.2	8.4
Capital Related-Machinery	3.8	3.9

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

b. Proposed Price Proxies for the 2016-Based ESRDB Market Basket

After developing the cost weights for the proposed 2016-based ESRDB market basket, we are proposing to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based the proposed price proxies on Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

(1) *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

(2) *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

(3) *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs were available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this helps to ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this provision meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 7 lists all price proxies for the proposed 2016-based ESRDB market

basket. We note that we are proposing to use the same proxies as those used in the 2012-based ESRDB market basket. Below is a detailed explanation of the price proxies used for each cost category weight.

Wages and Salaries

We are proposing to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the proposed 2016-based ESRDB market basket, and to continue using four occupational categories and associated ECIs based on full-time equivalents (FTE) data from ESRD MCRs and ECIs from BLS. We calculated occupation weights for the blended Wages and Salaries price proxy using 2016 FTE data from the MCR data and associated 2016 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics. This is similar to the methodology used in the 2012-based ESRDB market basket to derive these occupational wages and salaries categories.

Health Related

We are proposing to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU10262200000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (''Hospitals'' and ''Health Care and Social Assistance''), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.9 percent of total Wages and Salaries in 2016. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Health Related subcategory include ''Physicians,'' ''Registered Nurses,'' ''Licensed Practical Nurses,'' ''Nurses' Aides,'' ''Technicians,'' and ''Dieticians''.

Management

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU20200001100001). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities.

The Wages and Salaries—Management subcategory weight within the Wages and Salaries cost category is 6.7 percent in 2016. The ESRD Medicare Cost Report FTE category used to define the Wages and Salaries—Management subcategory is ''Management.''

Administrative

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU20200002200001). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities.

The Wages and Salaries—Administrative subcategory weight within the Wages and Salaries cost category is 7.7 percent in 2016. The ESRD MCR FTE category used to define the Wages and Salaries—Administrative subcategory is ''Administrative.''

Services

We propose using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU20200003000001). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-administrative service support personnel at ESRD facilities.

The Services subcategory weight within the Wages and Salaries cost category is 5.7 percent in 2016. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Services subcategory are ''Social Workers'' and ''Other.''

Table 6 lists the four ECI series and the corresponding weights used to construct the proposed ECI blend for Wages and Salaries compared to the 2012-based weights for the subcategories. We believe this ECI blend is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

TABLE 6—PROPOSED ECI BLEND FOR WAGES AND SALARIES IN THE PROPOSED 2016-BASED AND 2012-BASED ESRDB MARKET BASKETS

Cost category	ECI series	Proposed 2016 weight (percent)	2012 Weight (percent)
Health Related	ECI for Wages and Salaries for All Civilian Workers in Hospitals	79.9	79.0
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	6.7	8.0
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	7.7	7.0
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	5.7	6.0

Employee Benefits

We are proposing to continue using an ECI blend for Employee Benefits in the proposed 2016-based ESRDB market basket where the components match those of the proposed Wage and Salaries ECI blend. The proposed occupation weights for the blended Benefits price proxy are the same as those proposed for the wages and salaries price proxy blend as shown in Table 5. BLS does not publish ECI for Benefits price proxies for each Wage and Salary ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index.

Health Related

We are proposing to continue using the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU10162200000000I) and the relative importance of Wages and Salaries within Total Compensation as

published by BLS. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section.

Management

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2010000110000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section.

Administrative

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the wages and salaries price proxy section.

Services

We are proposing to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. We believe this ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section

We feel the proposed benefits ECI blend continues to be the most appropriate price proxy to measure the growth of benefits prices faced by ESRD facilities. Table 7 lists the four ECI series and the corresponding weights used to construct the proposed benefits ECI blend.

TABLE 7—PROPOSED ECI BLEND FOR BENEFITS IN THE PROPOSED 2016-BASED AND 2012-BASED ESRDB MARKET BASKETS

Cost category	ECI series	Proposed 2016 weight (percent)	2012 Weight (percent)
Health Related	ECI for Benefits for All Civilian Workers in Hospitals	79.9	79.0
Management	ECI for Benefits for Private Industry Workers in Management, Business, and Financial.	6.7	8.0
Administrative	ECI for Benefits for Private Industry Workers in Office and Administrative Support.	7.7	7.0
Services	ECI for Benefits for Private Industry Workers in Service Occupations	5.7	6.0

Electricity

We propose to continue using the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category.

Natural Gas

We propose to continue using the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category.

Water and Sewerage

We propose to continue using the CPI U.S. city average for Water and Sewerage Maintenance (BLS series code #CUUR0000SEHG01) to measure the price growth of this cost category.

Pharmaceuticals

We propose to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI–BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. We propose to continue using the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI–VNHP) (BLS series code #WPU063807) for all other drugs included in the bundle other than ESAs.

The PPI–BPHU measures the price change of prescription biologics, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI–BPHU and the ASP for ESAs and found the cumulative growth to be consistent over the past 4 years. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

Additionally, since the non-ESA drugs used in the treatment of ESRD are mainly vitamins and nutrients, we believe that the PPI–VNHP continues to be the best available proxy for these types of drugs. While this index does include over-the-counter drugs as well as prescription drugs, a comparison of trends in the prices for non-ESA drugs shows similar growth to the proposed PPI–VNHP.

Supplies

We propose to continue using the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category.

Lab Services

We propose to continue using the PPI Industry for Medical Laboratories (BLS series code #PCU621511621511) to measure the price growth of this cost category.

Telephone Service

We propose to continue using the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category.

Housekeeping and Operations

We propose to continue using the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category.

Professional Fees

We propose to continue using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code # CIU2010000120000I) to measure the price growth of this cost category.

All Other Goods and Services

We propose to continue using the PPI Commodity for Final demand—Finished Goods Less Foods and Energy (BLS series code #WPUFD4131) to measure the price growth of this cost category.

Capital-Related Building and Equipment

We propose to continue using the PPI Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) to measure the price growth of this cost category.

Capital-Related Machinery

We propose to continue using the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category.

Table 8 shows all the proposed price proxies and cost weights for the proposed 2016-based ESRDB Market Basket.

TABLE 8—PROPOSED PRICE PROXIES AND ASSOCIATED COST WEIGHTS FOR THE 2016-BASED ESRDB MARKET BASKET

Cost category	Price proxy	Proposed 2016 cost weight
Total ESRDB market basket		100.0
Compensation		43.6
Wages and Salaries		34.5
Health-related	ECI for Wages and Salaries for All Civilian Workers in Hospitals	27.6
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	2.3
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	2.7
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations	2.0
Employee Benefits		9.1
Health-related	ECI for Total Benefits for All Civilian workers in Hospitals	7.3
Management	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.6
Administrative	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.7
Services	ECI for Total Benefits for Private Industry workers in Service Occupations	0.5
Utilities		2.0
Electricity	PPI Commodity for Commercial Electric Power	1.1
Natural Gas	PPI Commodity for Commercial Natural Gas	0.1
Water and Sewerage	CPI–U for Water and Sewerage Maintenance	0.8
Medical Materials and Supplies		24.9
Pharmaceuticals		12.4
ESAs	PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use	10.0
Other Drugs	PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations	2.4
Supplies	PPI Commodity for Surgical and Medical Instruments	10.4
Lab Services	PPI Industry for Medical Laboratories	2.2
All Other Goods and Services		16.4
Telephone Service	CPI–U for Telephone Services	0.5
Housekeeping and Operations	PPI Commodity for Cleaning and Building Maintenance Services	3.9
Professional Fees	ECI for Total Compensation for Private Industry Workers in Professional and Related.	0.7
All Other Goods and Services	PPI for Final demand—Finished Goods less Foods and Energy	11.3
Capital Costs		13.0
Capital Related Building and Equipment.	PPI Industry for Lessors of Nonresidential Buildings	9.2
Capital Related Machinery	PPI Commodity for Electrical Machinery and Equipment	3.8

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

ii. Proposed CY 2019 ESRD Market Basket Update, Adjusted for Multifactor Productivity

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. We propose to use the 2016-based ESRDB market basket as described in this proposed rule to compute the CY 2019 ESRDB market basket increase factor and labor-related share. Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

a. Market Basket Update

Using this methodology and the IGI forecast for the first quarter of 2018 of the proposed 2016-based ESRDB market basket (with historical data through the fourth quarter of 2017), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2019 ESRDB market basket increase factor is 2.2 percent.

b. Multifactor Productivity (MFP)

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity

adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. The detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70235). The most up-to-date MFP projection methodology is available on the CMS website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. We are not proposing any changes to the methodology for the projection of the MFP adjustment.

Using IGI's first quarter 2018 forecast, the proposed MFP adjustment for CY 2019 (the 10-year moving average of MFP for the period ending CY 2019) is projected to be 0.7 percent.

c. Market Basket Update Adjusted for Multifactor Productivity (MFP)

As a result of these provisions, the proposed CY 2019 ESRD market basket increase is 1.5 percent. This market basket increase is calculated by starting with the proposed 2016-based ESRDB market basket percentage increase factor of 2.2 percent for CY 2019, and reducing it by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2019) of 0.7 percentage point. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket increase or MFP adjustment), we would use such data to determine the market basket increase and MFP adjustment in the CY 2019 ESRD PPS final rule.

The CY 2019 ESRDB increase factor would be the same if we used the 2012-based ESRDB market basket. That is, the CY 2019 ESRDB market basket increase factor is 2.2 percent using the 2012-based ESRDB market basket. Table 9 shows the increase factors under the proposed 2016-based ESRDB and 2012-based ESRDB market basket.

TABLE 9—HISTORICAL AND PROJECTED INCREASE FACTORS UNDER THE PROPOSED 2016-BASED AND 2012-BASED ESRDB MARKET BASKET

Calendar year (CY)	Proposed 2016-Based ESRDB market basket	2012-Based ESRDB market basket
Historical Data:		
CY 2015	2.0	2.2
CY 2016	1.9	2.0
CY 2017	1.4	1.3
Forecast:		
CY 2018	1.9	1.9
CY 2019	2.2	2.2

Source: IHS Global Inc. 1st quarter 2018 forecast with historical data through 4th quarter 2017.

iii. Proposed Labor-Related Share for ESRD PPS

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of Capital from a given market basket.

We propose to use the proposed 2016-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Therefore, effective for CY 2019, we are proposing a labor-related share of 52.3 percent, slightly higher than the current 50.673 percent that was based on the 2012-based ESRD market basket, as shown in Table 10 below. We propose to move the labor-related share to a one decimal level of precision rather than the three decimal level of precision used previously. CMS is migrating all payment system labor-related shares to a one decimal level of precision. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below). We used the same methodology for the 2012-based ESRD market basket.

TABLE 10—PROPOSED CY 2019 LABOR-RELATED SHARE AND CY 2018 LABOR-RELATED SHARE

Cost category	Proposed CY 2019 ESRD labor-related share	CY 2018 ESRD labor-related share
Wages and salaries	34.5	33.650
Employee Benefits	9.1	8.847
Housekeeping and Operations	3.9	3.785
Professional Fees (Labor-Related)	0.6	0.537
Capital Labor-Related	4.2	3.854
Total Labor-Related Share	52.3	50.673

The labor-related share for Professional Fees reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market (87 percent). We conducted a survey of ESRD facilities in

2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Thus, we are proposing to include 87 percent of the cost weight for Professional Fees in the labor-related share (87 percent is the same percentage as used in prior years).

The labor-related share for capital-related expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related Building and Equipment expenses). Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

b. The Proposed CY 2019 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/bulletins/*.

For CY 2019, we would update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The proposed CY 2019 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2019 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html*.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a decision to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which stakeholders could provide useful input for consideration in future decision-making. Specifically, we solicited comment on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, we finalized a wage index floor of 0.4000 in the CY 2017 ESRD PPS final rule (81 FR 77858).

In the CY 2018 final rule (82 FR 50747), we finalized a policy to permanently maintain the wage index floor of 0.4000, because we believed it was appropriate and provided additional payment support to the lowest wage areas. It also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates.

ii. Wage Index Floor for CY 2019 and Subsequent Years

For CY 2019 and subsequent years, we are proposing to increase the wage

index floor to 0.5. This wage floor increase is responsive to stakeholder comments, safeguards access to care in areas at the lowest end of the current wage index distribution, and is supported by data, as discussed below, which supports a higher wage index floor. Stakeholders, particularly those located in Puerto Rico, have expressed the adverse impact the low wage index floor value has on a facility, such as closure and the resulting impact on access to care. Also, natural disasters (for example, hurricanes, floods) common to this geographic area can cause significant infrastructure issues, create limited resources, and create conditions that may accelerate kidney failure in patients predisposed to chronic kidney disease, all of which have a significant impact on renal dialysis services. These negative effects of natural disasters on the local economy impact wages and salaries. For example, there is the potential of the outmigration of qualified staff that would cause a facility the need to change their hiring practices or increase the wages that they would otherwise pay had their not been a natural disaster.

In response to the CY 2018 ESRD proposed rule, commenters described the economic and healthcare crisis in Puerto Rico and recommended that CMS use the U.S. Virgin Islands wage index for payment rate calculations in Puerto Rico as a proxy for CY 2018.

Commenters indicated that the primary issue is that Puerto Rico hospitals report comparatively lower wages that are not adjusted for occupational mix and, as indicated in the CY 2017 ESRD PPS proposed rule (81 FR 42817), in Puerto Rico, only registered nurses (RNs) can provide dialysis therapy in the outpatient setting. This staffing variable artificially lowers the reportable index values even though the actual costs of dialysis service wages in Puerto Rico are much higher than the data CMS is relying upon. In addition, several commenters stated that non-labor costs, including utilities and shipping costs and the CY 2015 change in the labor-share based on the rebased and revised ESRDB market basket compound the issue even further.

One organization stated that it does not believe maintaining the current wage index for Puerto Rico for CY 2018 is enough to offset the poor economic conditions, high operational costs and epidemiologic burden of ESRD on the island.

Since we did not propose to change the wage index floor or otherwise change the wage indexes for Puerto Rico, we maintained the wage index floor of 0.4000 for CY 2018. We noted that the current wage index floor and labor-related share have been in effect since CY 2015 and neither the floor nor the labor share has been reduced since then. More importantly, the wage index is solely intended to reflect differences in labor costs and not to account for non-labor cost differences, such as utilities or shipping costs (82 FR 50747).

With regard to staffing in Puerto Rico facilities, we noted that ESRD facilities there utilize RNs similarly to ESRD facilities on the mainland, that is, facilities utilize dialysis technicians and aides to provide dialysis services with oversight by an RN and that hourly wages for RNs and dialysis support staff were approximately half of those salaries in mainland ESRD facilities. For those reasons, we do not agree that the hospital-reported data is unreliable, and we believe using that data is more appropriate than applying the wage index value for the Virgin Islands where salaries are considerably higher.

Even though we did not propose a change in the wage index floor for CY 2018, we continued to analyze the cost of furnishing dialysis care in Puerto Rico, staffing in Puerto Rico ESRD facilities and hospital wage data. While we found the analyses to be inconclusive for the CY2018 ESRD PPS final rule (82 FR 50746), in light of the recent natural disasters that profoundly impacted delivery of ESRD care in Puerto Rico, we revisited the analyses and concluded that we should propose a new wage index floor. We conducted various analyses to test the reasonableness of the current wage index floor value of 0.4000. The details of these analyses and our proposal are provided below.

a. Analysis of Puerto Rico Cost Reports

We performed an analysis using cost reports and wage information specific to Puerto Rico from the BLS (*https://www.bls.gov/oes/2015/may/oes_pr.htm*). The analysis used data from cost reports for freestanding facilities and hospital-based facilities in Puerto Rico for CYs 2013 through 2015 are as follows:

- The analysis utilized data from cost reports for freestanding facilities and for hospital-based facilities. Note that the available variables differ between these two sources. For freestanding facilities, data were obtained regarding treatment counts, costs, salaries, benefits, and FTEs by labor category. For hospital-based facilities, a more limited set of variables are available for treatment counts and FTEs.
- We annualized cost report data for each facility in order to create one cost report record per facility per calendar. If cost report forms were submitted at a non-calendar-year cycle, multiple cost report records were proportionated and combined in order to create an annualized cost report record.
- We calculated weighted means across all facilities for each variable. The means were weighted by treatment counts, where facilities with more treatment counts contributed more to the value of the overall mean.

Using this data, we calculated alternative wage indices for Puerto Rico that combined labor quantities (FTEs) from cost reports with BLS wage information to create two regular Laspeyres price indexes. The Laspeyres index can be thought of as a price index in which there are two prices for goods (prices for labor FTEs in Puerto Rico and the mainland U.S.), where the distribution of goods (labor share of FTEs) is held constant (across Puerto Rico and the U.S.). The first index used quantity weights from the overall U.S. use of labor inputs. The second index used quantity weights from the PR use of labor inputs.

The alternative wage indices derived from the analysis indicate that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. Both of these values are above the current wage index floor and suggest that the current 0.4000 wage index floor may be too low.

b. Statistical Analysis of the Distribution of the Wage Index

We also performed a statistical outlier analysis to identify the upper and lower boundaries of the distribution of the current wage index values and remove outlier values at the edges of the distribution.

In the general sense, an outlier is an observation that lies an abnormal distance from other values in a population. In this case, the population of values is the various wage indices within the CY 2019 wage index. The lower and upper quartiles (the 25th and 75th percentiles) are also used. The lower quartile is Q1 and the upper quartile is Q3. The difference (Q3 − Q1) is called the interquartile range (IQR). The IQR is used in calculating the inner and outer fences of a data set. The inner fences are needed for identifying mild outlier values in the edges of the distribution of a data set. Any values in the data set that are outside of the inner fences are identified as an outlier. The standard multiplying value for identifying the inner fences is 1.5.

First, we identified the Q1 and Q3 quartiles of the CY 2018 wage index, which are as follows: Q1 = 0.8303 and Q3 = 0.9881. Next, we identified the

IQR: IQR = 0.9881 − 0.8303 = 0.578. Finally, we identified the inner fence values as shown below.

Lower inner fence: Q1 − 1.5 * IQR = 0.8303 − (1.5 × 0.1578) = 0.5936

Upper inner fence: Q3 + 1.5 * IQR = .881 + (1.5 × 0.1578) = 1.2248

This statistical outlier analysis demonstrates that any wage index values less than 0.5936 are considered outlier values, and 0.5936 as the lower boundary also may suggest that the current wage index floor could be appropriately reset at a higher level.

Based on these analyses, we are proposing a wage index floor of 0.5000. We believe this increase from the current 0.4000 wage index floor value minimizes the impact to the base rate while providing increased payment to areas that need it. We considered the various wage index floor values based on our analyses. While the statistical analysis supports our decision to propose a higher wage index floor, the cost report analysis is more definitive as it is based on reported wages using an alternative data source. As a result, we considered wage index floor values between 0.4000 and 0.5500 and are proposing 0.5000 in an effort to strike a balance between providing additional payments to affected areas while minimizing the impact on the base rate. We believe the proposed 25 percent increase from the current 0.4000 value would help to address stakeholder requests for a higher wage index floor, minimize patient access issues, and would have a lower impact to the base rate than if we proposed a higher wage index floor value.

The wage index floor directly affects the base rate and currently, only rural Puerto Rico and four urban CBSAs in Puerto Rico receive the wage index floor of 0.4000. The next lowest wage index is in the Wheeling, West Virginia CBSA with a value of 0.6599. Under this proposal, all CBSAs in Puerto Rico would receive the wage index floor of 0.5000. Though the proposed wage index value currently affects CBSAs in Puerto Rico, we note that, consistent with our established policy, any CBSA that falls below the floor would be eligible to receive the floor. We solicit comment on the proposal to increase the wage index floor from 0.4000 to 0.5000 for CY 2019 and beyond.

iii. Application of the Wage Index Under the ESRD PPS

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In section II.B.3.b of this proposed rule, we are proposing the labor-related share of 52.3 percent, which is based on the proposed 2016-based ESRDB market basket. Thus, for CY 2019, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

iv. New Urban Core-Based Statistical Area (CBSA)

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB Web site at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. We did not have sufficient time to include this change in the computation of the proposed CY 2019 wage index, rate setting, and Addenda associated with this proposed rule. This new CBSA may affect the budget neutrality factors and wage indexes, depending on the impact of the overall payments of the hospital located in this new CBSA. In this proposed rule, we are providing an estimate of this new area's wage index based on the average hourly wage, unadjusted for occupational mix, for new CBSA 46300 and the national average hourly wages from the wage data for the proposed CY 2019 wage index. Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

Taking the estimated unadjusted average hourly wage of $35.833564813 of the new CBSA 46300 and dividing by the national average hourly wage of $42.990625267 results in the proposed estimated wage index of 0.8335 for CBSA 46300.

In the final rule, we would incorporate this change into the final CY 2019 ESRD PPS wage index, rate setting and Addenda associated with the final rule. Thus, for CY 2019, we would use the OMB delineations that were adopted beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01.

c. Proposed CY 2019 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by

Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described below) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For CY 2019, we propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2017. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we propose the outlier thresholds for CY 2019 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2017. We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS.

In the CY 2018 ESRD PPS final rule (82 FR 50748), we stated that based on the CY 2016 claims data, outlier payments represented approximately 0.78 percent of total payments. For this proposed rule, as discussed below, CY 2017 claims data show outlier payments represented approximately 0.80 percent of total payments.

i. CY 2019 Update to the Outlier Services Medicare Allowable Payment (MAP) Amounts and Fixed Dollar Loss (FDL) Amounts

For CY 2019, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2017 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2017 claims data. The impact of this update is shown in Table 11, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2017 with the updated proposed estimates for this rule. The estimates for the proposed CY 2019 outlier policy, which are included in Column II of Table 11, were inflation adjusted to reflect projected 2019 prices for outlier services.

TABLE 11—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Final outlier policy for CY 2018 (based on 2016 data, price inflated to 2018)*		Column II Proposed outlier policy for CY 2019 (based on 2017 data, price inflated to 2019)	
	Age <18	Age >=18	Age <18	Age >=18
Average outlier services MAP amount per treatment	37.41	44.27	34.33	41.97
Adjustments				
Standardization for outlier services	1.0177	0.9774	1.0588	0.9786
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$37.31	$42.41	$35.62	$40.25
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$47.79	$77.54	$47.88	$69.73
Patient-months qualifying for outlier payment	9.0%	7.4%	9.2%	8.0%

* Note that Column I was obtained from Column II of Table 1 from the CY 2018 ESRD PPS final rule (82 FR 50749).

As demonstrated in Table 11, the estimated FDL amount per treatment that determines the CY 2019 outlier threshold amount for adults (Column II; $69.73) is lower than that used for the CY 2018 outlier policy (Column I; $77.54). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $42.41 to $40.25. For pediatric patients, there is a slight increase in the FDL amount from $47.79 to $47.88. There is a corresponding decrease in the adjusted average MAP

for outlier services among pediatric patients, from $37.31 to $35.62.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2019 will be 8.0 percent for adult patients and 9.2 percent for pediatric patients, based on the 2017 claims data. The pediatric outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2017 claims, outlier payments represented approximately 0.80 percent of total payments, slightly below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2017 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2019. We believe the update to the outlier MAP and FDL amounts for CY 2019 would increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy because we are using more current data for computing the MAP and FDL which is more in line with current outlier services utilization rates. We note that recalibration of the FDL amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments, as well as co-insurance obligations for beneficiaries with renal dialysis services eligible for outlier payments.

iii. Solicitation on the Expansion of the Outlier Policy

Currently, former separately payable Part B drugs, laboratory services, and supplies are eligible for the outlier payment. In the interest of promoting innovation, ensuring appropriate payment for all drugs and biologicals, and as a complement to the TDAPA proposals, we are soliciting comment on whether we should expand the outlier policy to include composite rate drugs and supplies. With the proposed expansion to the drug designation process discussed in section II.B.1.f of this proposed rule, such expansion of the outlier policy could promote appropriate payment for composite rate drugs once the TDAPA period has ended. Additionally, with regard to composite rate supplies, an expansion of the outlier policy could promote use of new innovative devices or items that would otherwise be considered in the bundled payment. If commenters believe such an approach is appropriate, we are requesting they provide input on how we would effectuate such a shift in policy. For example, the reporting of these services may be challenging since they have never been reported on ESRD claims previously. We are particularly interested in feedback about how such items might work under the existing outlier framework or whether specific changes to the policy to accommodate such items are needed. We will consider all comments and address by making proposals, if appropriate, in future rulemaking.

d. Proposed Impacts to the CY 2019 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the per-treatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment and training adjustment add-on.

ii. Annual Payment Rate Update for CY 2019

We are proposing an ESRD PPS base rate for CY 2019 of $235.82. This update reflects several factors, described in more detail as follows:

- *Market Basket Increase:* Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2019 projection for the proposed ESRDB market basket is 2.2 percent. In CY 2019, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed above, the proposed MFP adjustment for CY 2019 is 0.7 percent, thus yielding a proposed update to the base rate of 1.5 percent for CY 2019. Therefore, the proposed ESRD PPS base rate for CY 2019 before application of the wage index budget-neutrality adjustment factor would be $235.86 ($232.37 × 1.0150 = $235.86).

- *Wage Index Budget-Neutrality Adjustment Factor:* We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2019, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2019 wage index budget-neutrality adjustment factor using treatment counts from the 2017 claims and facility-specific CY 2018 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2018. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2019. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2019. The total of these payments becomes the new CY 2019 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2019 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2019 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate

Medicare payments with respect to changes in wage index updates.

The CY 2019 proposed wage index budget-neutrality adjustment factor is 0.999833. This application would yield a CY 2019 ESRD PPS proposed base rate of $235.82 ($235.75 × 0.999833 = $235.82).

In summary, we are proposing a CY 2019 ESRD PPS base rate of $235.82. This amount reflects a proposed market basket increase of 1.5 percent and the proposed CY 2019 wage index budget-neutrality adjustment factor of 0.999833.

C. Solicitation for Information on Transplant and Modality Requirements

When an individual is faced with failing kidneys, life-extending treatment is available. The most common treatment is dialysis, but the best treatment is receiving a kidney transplant from a living or deceased donor. Dialysis, either HD or PD, can sustain life by removing impurities and extra fluids but cannot do either job as consistently or efficiently as a functioning kidney. Dialysis also carries risks of its own, including anemia, bone disease, hypotension, hypertension, heart disease, muscle cramps, itching, fluid overload, nerve damage, depression, and infection. Timely transplantation, despite requiring a major surgery and ongoing medication, offers recipients a longer, higher quality of life, without the ongoing risks of dialysis. Unfortunately, the number of people waiting for healthy donor kidneys far exceeds the number of available organs. In 2015, the most recent year for which complete data is available, 18,805 kidney transplants were performed in the U.S., while over 80,000 individuals remained on waiting lists (*https://www.usrds.org/2017/view/v2_06.aspx*). That same year, there were 124,114 newly reported cases of ESRD and over 703,243 prevalent cases of ESRD (*https://www.usrds.org/2017/view/v2_01.aspx*).

In recognition of the superiority of transplantation but the need for dialysis, CMS has required for nearly 10 years that Medicare-certified dialysis facilities evaluate all patients for transplant suitability and make appropriate referrals to local transplant centers (73 FR 20370). Specifically, dialysis facilities must:

- Inform every patient about all treatment modalities, including transplantation (§ 494.70(a)(7)).
- Evaluate every patient for suitability for a transplantation referral (§ 494.80(b)(10)).
- Document any basis for non-referral in the patient's medical record (§ 494.80(b)(10)).
- Develop plans for pursuing transplantation for every patient who is a transplant referral candidate (§ 494.90(a)(7)(ii)).
- Track the results of each kidney transplant center referral (§ 494.90(c)(1)).
- Monitor the status of any facility patients who are on the transplant waitlist (§ 494.90(c)(2)).
- Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status (§ 494.90(c)(3)).
- Educate patients, family members, or caregivers or both about transplantation, as established in a patient's plan of care (§ 494.90(d)).

Despite these requirements, the percentage of prevalent dialysis patients wait-listed for a kidney has recently declined (*https://www.usrds.org/2017/view/v2_06.aspx*, Figure 6.2), meaning that fewer people have the opportunity to be matched with a donor kidney. Some individuals do receive kidneys directly from suitable friends or family members, but still must be placed on the waiting list. Organ Procurement and Transplantation Network (OPTN) policy requires that all transplant recipients, including recipients of organs from living donors, be registered and added to the OPTN waiting list. Until a dialysis patient is referred to a transplant center, he or she is not able to be placed on the waiting list, and is ineligible to receive a kidney. While dialysis facilities have no control over the total supply of kidneys made available for transplantation, transplantation education, referral, and waitlist tracking are appropriate and necessary services for them to furnish. Unfortunately, there are performance gaps and disparities between dialysis facilities in providing these services.[3] Therefore, as discussed in section IV.C.1.a. of section IV ''End-Stage Renal Disease Quality Incentive Program (ESRD QIP)'' of this proposed rule, we are proposing a reporting measure under the ESRD QIP that would track the percentage of patients at each dialysis facility who are on the kidney or kidney-pancreas transplant waiting list. We are also soliciting input on other ways to increase kidney transplant referrals and improve the tracking process for patients on the waitlist:

- Are there ways to ensure facilities are meeting the Conditions for Coverage (CfC) requirements, in addition to the survey process?
- Are the current dialysis facility CfC requirements addressing transplantation support services adequately, or should additional requirements be considered?

We welcome your input.

With regard to other treatment for failed kidneys, HD performed in an outpatient dialysis center is most common, followed by HD performed at home, and PD (almost always performed at home). Just as we are concerned about disparities in access to transplantation, we are also concerned about disparities in access to dialysis modality options. Although ESRD disproportionately affects racial and ethnic minority patients, minority individuals are far less likely to be treated with home dialysis than white patients.[4] Home dialysis modalities necessitate a higher level of self-care than in-center care, and are not appropriate for or desired by every dialysis patient. We are concerned, however that not all dialysis patients are aware of, or given the opportunity to learn about, home modalities or their benefits—primarily greater independence and flexibility. Individuals performing home dialysis treatments are able to schedule their treatments at times most convenient for them, allowing them to coordinate with family and work schedules, and eliminate the need for thrice weekly transportation to and from a dialysis facility. The transportation savings are especially valuable to rural individuals, who might have to travel hours each week for regular treatments in a facility.

We take this opportunity to remind dialysis facilities of their responsibilities regarding modality education and options. Some dialysis facilities do not support home modalities, but all facilities are required to make appropriate referrals if a patient elects to pursue home treatments. Specifically, dialysis facilities must:

- Inform every patient about all treatment modalities, including transplantation, home dialysis modalities (home HD, intermittent PD, continuous ambulatory PD, continuous

[3] R.E. Patzer, L. Plantinga, J. Krisher, S.O. Pastan, ''Dialysis facility and network factors associated with low kidney transplantation rates among U.S. dialysis facilities,'' American Journal of Transplantation, 2014 Jul; 14(7):1562–72; and Sudeshna Paul, Laura C. Plantinga, Stephen O. Pastan, Jennifer C. Gander, Sumit Mohan, and Rachel E. Patzer, ''Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities,'' Clinical Journal of the American Society of Nephrology, January 2018.

[4] Mehrotra, R., Soohoo, M., Rivara, M.B., Himmelfarb, J., Cheung, A.K., Arah, O.A., Nissenson, A.R., Ravel, V., Streja, E., Kuttykrishnan, S., Katz, R., Molnar, M., Kalantar-Zadeh, K., ''*Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States,*'' Journal of the American Society of Nephrology December 10, 2015.

cycling PD), and in-facility HD (§ 494.70(a)(7)).

- Ensure all patients are provided access to resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients (§ 494.70(a)(7)).
- Assess every patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes (§ 494.80(a)(9)).
- Identify a plan for every patient's home dialysis or explain why the patient is not a candidate for home dialysis (§ 494.90(a)(7)(i)).
- Provide education and training, as applicable, to patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types (§ 494.90(d)).

Persons with failed kidneys often begin dialysis with no prior exposure to nephrology care or knowledge of treatment options. The practitioners and professionals who care for them are best suited to provide the necessary information to support informed, shared decision-making. Patient education is not a one-time incident, but an ongoing aspect of all health care services and settings. We welcome your suggestions on ways to ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities.

III. CY 2019 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA), Public Law 114–27, was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Annual Payment Rate Update for CY 2019

1. CY 2019 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including market basket adjustments, wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.3.d of this proposed rule, the CY 2019 proposed ESRD PPS base rate is $235.82, which reflects the proposed ESRD bundled market basket and multifactor productivity adjustment. Accordingly, we are proposing a CY 2019 per treatment payment rate of $235.82 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.3.f of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated above, we are proposing a CY 2019 AKI dialysis payment rate of $235.82, adjusted by the ESRD facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the calendar year (CY) 2018 ESRD Prospective Payment System (PPS) final rule (82 FR 50756 through 50757).

1. Improving Patient Outcomes and Reducing Burden Through the Meaningful Measures Initiative

Regulatory reform and reducing regulatory burden are high priorities for the Centers for Medicare & Medicaid Services (CMS). To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[5] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[6] which is aimed at evaluating and streamlining

[5] Meaningful Measures webpage: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html*.

[6] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html*.

regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that will foster operational efficiencies and will reduce costs, including collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Initiative has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 12.

TABLE 12—QUALITY PRIORITY ASSOCIATED WITH MEANINGFUL MEASURE AREAS

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections.
	Preventable Healthcare Harm.
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals.
	End of Life Care According to Preferences.
	Patient's Experience of Care.
	Patient Reported Functional Outcomes.
Promote Effective Communication and Coordination of Care	Medication Management.
	Admissions and Readmissions to Hospitals.
	Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care.
	Management of Chronic Conditions.
	Prevention, Treatment, and Management of Mental Health.
	Prevention and Treatment of Opioid and Substance Use Disorders.
	Risk Adjusted Mortality.
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care.
	Community Engagement.
Make Care Affordable	Appropriate Use of Healthcare.
	Patient-focused Episode of Care.
	Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

2. Accounting for Social Risk Factors in the ESRD QIP

In the fiscal year (FY) 2018 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule (82 FR 38237 through 38239), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by the Department of Health and Human Services, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[7] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing (VBP) programs.[8] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), ASPE's report to Congress found that, in the context of VBP programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these

[7] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[8] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

measures.[9] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[10] allowing further examination of social risk factors in outcome measures.

In the FY 2018 IPPS/LTCH PPS and CY 2018 ESRD PPS proposed rules for our quality reporting and VBP programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to VBP programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that VBP program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting (IQR) Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. Proposal To Update Regulation Text for the ESRD QIP

We are proposing to codify a number of previously adopted requirements for the ESRD QIP in our regulations by revising § 413.177 and adopting a new § 413.178. Codification of these requirements would make it easier for the public to locate these requirements. Proposed § 413.178 would codify the following:

- Definitions of key terms used in the ESRD QIP;
- Rules for determining the applicability of the ESRD QIP to facilities, including new facilities;
- Measure selection;
- Rules governing performance scoring, including how we calculate the total performance score;
- Our process for making ESRD QIP performance information available to the public; and
- The limitation on administrative and judicial review.

Revised § 413.177(a) would codify that an ESRD facility that does not earn enough points under the ESRD QIP to meet or exceed the minimum total performance score established for a payment year would receive up to a 2 percent reduction to its otherwise applicable payment amount under the ESRD PPS for renal dialysis services furnished during that payment year.

We welcome public comments on the proposed regulation text.

B. Proposed Update to Requirements Beginning With the PY 2021 ESRD QIP

1. Proposal To Update the PY 2021 Measure Set

In this proposed rule, we are proposing to refine and update the criteria for removing measures from the ESRD QIP measure set, and for consistency with the terminology we are adopting for other CMS quality reporting and value-based purchasing programs, we now refer to these criteria as factors. We are also proposing to remove four of the reporting measures that we previously finalized for the PY 2021 ESRD QIP measure set. Table 13 summarizes the proposed revisions to the PY 2021 ESRD QIP measure set, and we discuss the measure removal proposals in section IV.B.1.c of this proposed rule.

TABLE 13—PROPOSED REVISIONS TO THE PREVIOUSLY FINALIZED PY 2021 ESRD QIP MEASURE SET

NQF #	Measure title and description	Measure continuing in PY 2021
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.	Yes.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.	Yes.

[9] Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[10] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

TABLE 13—PROPOSED REVISIONS TO THE PREVIOUSLY FINALIZED PY 2021 ESRD QIP MEASURE SET—Continued

NQF #	Measure title and description	Measure continuing in PY 2021
2979	Standardized Transfusion Ratio (STrR), a clinical measure Risk-adjusted TrR for all adult Medicare dialysis patients. Number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.	Yes.
N/A	A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume (Kt/V) Dialysis Adequacy Comprehensive, a clinical measure. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.	Yes.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure. Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.	Yes.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure. Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.	Yes.
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.	Yes.
1463*	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.	Yes.
0255	Serum Phosphorus, a reporting measure. Percentage of all adult (≥18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum of plasma phosphorus measured at least once within month.	Proposed for Removal.
N/A	Anemia Management Reporting, a reporting measure. Number of months for which facility reports erythropoiesis-stimulating agent (ESA) dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient, at least once per month.	Proposed for Removal.
Based on NQF #0420	Pain Assessment and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.	Proposed for Removal.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.	Yes.
Based on NQF #0431	National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination, a reporting measure. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to the Centers for Disease Control and Prevention's (CDC's) NHSN system, according to the specifications of the Healthcare, Personnel Safety Component Protocol by May 15 of the performance period.	Proposed for Removal.
N/A	Ultrafiltration Rate, a reporting measure Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.	Yes.
Based on NQF #1460	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.	Yes.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to CDC.	Yes.

a. Proposal To Refine and Update the Factors Used for ESRD QIP Measure Removal

Under our current policy, we consider an ESRD QIP measure for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY

2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure set would address the unique needs of a specific subset of the ESRD population (79 FR 66174). In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized that we would generally remove an ESRD QIP measure using notice and comment rulemaking, unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we stated that we would immediately notify ESRD facilities and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings.

In order to align with terminology we are adopting for use across a number of quality reporting and pay for performance programs, we will now refer to these criteria as ''factors'' rather than ''criteria.'' We are also proposing to update these measure removal factors so that they are more closely aligned with the factors we have adopted or proposed to adopt for other quality reporting and pay for performance programs, as well as the priorities we have adopted as part of our Meaningful Measures Initiative. Specifically, we are proposing to combine current Factors 4 and 5 (proposed new Factor 4), and we are proposing to adjust the numbering of subsequent factors to account for this change. We are also proposing to add a new factor for measures where it is not feasible to implement the measure specifications; we would refer to this new factor as Factor 7. Proposed Factors 1 through 7 are as follows:

- Factor 1. Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (for example, the measure is topped-out).
- Factor 2. Performance or improvement on a measure does not result in better or the intended patient outcomes.
- Factor 3. A measure no longer aligns with current clinical guidelines or practice.
- Factor 4. A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.
- Factor 5. A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.
- Factor 6. Collection or public reporting of a measure leads to negative or unintended consequences.
- Factor 7. It is not feasible to implement the measure specifications.

We believe these proposed updates would better ensure that we use a consistent approach across our quality reporting and value-based purchasing programs when considering measures for removal, and that they reflect the considerations we have long used when evaluating measures for removal from the ESRD QIP. However, even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality, or in the event that a given measure is statutorily required. Furthermore, consistent with other quality reporting programs, we propose to apply these factors on a case-by-case basis.

We welcome comment on these proposals.

b. Proposed New Measure Removal Factor

In this proposed rule, we are proposing to adopt an additional factor to consider when evaluating measures for removal from the ESRD QIP measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the Program.

As we discuss in section IV.A.1 of this proposed rule, with respect to our new ''Meaningful Measures Initiative,'' we are engaging in efforts to ensure that the ESRD QIP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the Program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the Program. We have identified several different types of costs, including, but not limited to: (1) Provider, supplier and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) provider, supplier and clinician cost associated with complying with other quality programmatic requirements; (3) provider, supplier and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) CMS cost associated with the Program oversight of the measure, including measure maintenance and public display; and (5) provider, supplier and clinician cost associated with compliance with other federal and/or state regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports Program objectives (for example, informing beneficiary choice). It may also be costly for health care providers to track confidential feedback preview reports and publicly reported information on a measure where we use the measure in more than one Program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different Programs.

When these costs outweigh the evidence supporting the continued use of a measure in the ESRD QIP, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the ESRD QIP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the ESRD QIP may better accommodate the costs of Program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the Program forward in the least burdensome manner possible, while maintaining an appropriately sized set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal factor, ''the costs associated with a measure outweigh the benefit of its continued use in the Program,'' beginning with PY 2021.

c. Proposed Removal of Four Reporting Measures

We have undertaken efforts to review the existing ESRD QIP measure set in the context of the Meaningful Measures Initiative described in section IV.A.1 of this proposed rule. Based on that analysis and our evaluation of the Program's measures, we are proposing to remove four measures previously adopted for the ESRD QIP, starting with PY 2021. If these proposals are finalized, facilities would no longer be required to report data specific to these measures beginning with January 1, 2019 dates of service. The four measures we are proposing to remove from the ESRD QIP measure set are:

- Healthcare Personnel Influenza Vaccination.
- Pain Assessment and Follow-Up.
- Anemia Management.
- Serum Phosphorus.

Proposed Removal of the Healthcare Personnel Influenza Vaccination Reporting Measure From the ESRD QIP Measure Set

In the CY 2015 ESRD PPS final rule, we adopted the Healthcare Personnel Influenza Vaccination reporting measure in the ESRD QIP measure set beginning with PY 2018 because we recognize that influenza immunization is an important public health issue and that vaccinating healthcare personnel against influenza can help to protect healthcare personnel and their patients (79 FR 66206 through 66208). We continue to believe that the Healthcare Personnel Influenza Vaccination measure provides the benefit of protecting patients against influenza. However, our analysis of CY 2016 data indicates that ESRD facility performance on the measure was consistently high; 98 percent of ESRD facilities received the highest possible score on the measure (10 points) and the remaining 2 percent received no score on the measure because they did not report the required data. This finding indicates that influenza vaccination of healthcare personnel in ESRD facilities is a widespread practice and that there is little room for improvement on this measure. Accordingly, we are proposing to remove this measure from the ESRD QIP measure set beginning with PY 2021 under Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Proposed Removal of the Pain Assessment and Follow-Up Reporting Measure From the ESRD QIP Measure Set

In the CY 2015 ESRD PPS final rule, we adopted the Pain Assessment and Follow-Up reporting measure beginning with PY 2018 (79 FR 66203 through 66206) because patients with ESRD frequently experience pain that has a debilitating impact on their daily lives, and research has shown a lack of effective pain management strategies in place in dialysis facilities. We continue to believe that effective pain management is an important component of the care received by ESRD patients. However, our analysis of CY 2016 data indicates that with respect to that year, 90 percent of ESRD facilities received the highest possible score on the measure (10 points) and 1 percent of ESRD facilities received no score on the measure. This finding indicates that documentation of pain management using a standardized tool, as well as documentation of a follow-up plan where pain is present, are widespread practices in ESRD facilities and that there is little room for improvement on the measure. Accordingly, we are proposing to remove this measure from the ESRD QIP measure set based on our proposed Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Proposed Removal of the Anemia Management Reporting Measure From the ESRD QIP Measure Set

In the CY 2013 ESRD PPS final rule, we adopted the Anemia Management reporting measure beginning with the PY 2015 ESRD QIP (77 FR 67491 through 67495) because we believe that it is important to monitor hemoglobin levels in patients to ensure that anemia is properly treated. Additionally, the measure's adoption fulfilled the statutory requirement at section 1881(h)(2)(A)(i) of the Act that the ESRD QIP include measures on anemia management that reflect labeling approved by the Food and Drug Administration (FDA) for such management. Additionally, in the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197), we adopted the NQF-endorsed Standardized Transfusion Ratio (STrR) measure beginning with PY 2018 to ensure that patients with ESRD are not negatively affected by underutilization of ESAs, with the result that these patients have lower achieved hemoglobin levels and more frequently need red-blood-cell transfusions. We stated that there is a strong association between achieved hemoglobin levels and subsequent transfusion events, and that facilities have a direct role in determining achieved hemoglobin as a result of their anemia management practices (79 FR 66194). We also noted that the STrR measure meets the requirement at section 1881(h)(2)(A)(i) of the Act for the ESRD QIP to adopt measures of anemia management that reflect the labeling approved by the Food and Drug Administration for such management.

Our analysis of CY 2016 data indicates that ESRD facility performance on the Anemia Management reporting measure was consistently high; 96 percent of ESRD facilities received the highest possible score on the measure (10 points). This finding indicates that facility tracking of hemoglobin values and, as applicable, ESA dosages, is widely performed among ESRD facilities and that there is little room for improvement on the measure.

We are therefore proposing to remove the Anemia Management reporting measure from the ESRD QIP measure set based on Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Proposed Removal of the Serum Phosphorus Reporting Measure From the ESRD QIP Measure Set

In the CY 2014 ESRD PPS final rule, we adopted the Hypercalcemia measure beginning with the PY 2016 ESRD QIP (78 FR 72200 through 72203) as a measure of bone mineral metabolism. Specifically, this measure assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average. In the CY 2017 ESRD PPS final rule (81 FR 77876 through 77879), we finalized two modifications to the measure's technical specifications, as recommended during the measure maintenance process at the NQF, beginning with PY 2019. First, we added plasma as an acceptable substrate in addition to serum calcium. Second, we amended the denominator definition to include patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. These changes ensure that, beginning with PY 2019, the measure aligns with the NQF-endorsed measure.

In the CY 2017 ESRD PPS final rule, we adopted a second measure of bone

mineral metabolism, beginning with PY 2020: The Serum Phosphorus reporting measure (81 FR 77911 through 77912). This measure evaluates the extent to which facilities monitor and report patient phosphorus levels.

While we consider both the Hypercalcemia measure and the Serum Phosphorus measure to be measures of bone mineral metabolism, the two measures track different minerals. Hypercalcemia measures calcium levels and Serum Phosphorus measures phosphorus levels. Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calcium-phosphorus dysregulation (81 FR 77911).

As a result of the NQF's 2017 re-endorsement of the Hypercalcemia measure, as well as the Hypercalcemia measure's focus on clinical factors that are more directly under the facility's control, we now consider the Hypercalcemia measure to be a superior measure of bone mineral metabolism compared with Serum Phosphorus. In addition, of the two measures, the Hypercalcemia measure is more focused on outcomes; the Serum Phosphorus is a reporting measure while the Hypercalcemia measure is a clinical measure. Finally, the Hypercalcemia measure is an outcome-based measure specific to the conditions treated with oral-only drugs, which is a statutory requirement for the ESRD QIP measure set. Based on the limited benefit provided to the Program by the Serum Phosphorus measure as well as its reporting burden, we are proposing to remove the Serum Phosphorus reporting measure from the ESRD QIP measure set based on Factor 5 (that is, a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available).

We seek comments on these proposals. We note that we are not proposing any changes to the PY 2021 performance period or performance standards, and we refer readers to the CY ESRD PPS 2018 final rule (82 FR 50778 through 50779) for a discussion of those policies.

2. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2021 ESRD QIP

In the CY 2018 ESRD PPS final rule (82 FR 50763 through 50764) we finalized that for PY 2021, the performance standards, achievement thresholds, and benchmarks for the clinical measures would be set at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2017, because this would give us enough time to calculate and assign numerical values to those performance standards prior to the beginning of the performance period for that payment year. At this time, we do not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2017. Nevertheless, we are able to estimate these numerical values based on the most recent data available. In Table 14, we have provided the estimated numerical values for all finalized PY 2021 ESRD QIP clinical measures, and we note that we have not proposed in this proposed rule to remove any of those measures. We will publish updated values for the clinical measures, using CY 2017 data that facilities submitted in the first part of CY 2018, in the CY 2019 ESRD PPS final rule.

TABLE 14—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2021 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type:			
Standardized Fistula Rate	0.518	0.752	0.628
Long-Term Catheter Rate	19.23%	5.47%	12.02%
Kt/V Composite	91.09%	98.56%	95.64%
Hypercalcemia	2.41%	0.00%	0.86%
Standardized Transfusion Ratio	1.683	0.200	0.846
Standardized Readmission Ratio	1.273	0.630	0.998
NHSN BSI	1.598	0	0.740
SHR measure	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	57.36%	78.09%	67.04%
ICH CAHPS: Quality of Dialysis Center Care and Operations	53.14%	71.52%	61.22%
ICH CAHPS: Providing Information to Patients	73.31%	86.83%	79.79%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.84%	77.42%	62.26%
ICH CAHPS: Overall Rating of the Dialysis Facility	52.24%	82.48%	66.82%

Data sources: VAT measures: 2016 CROWNWeb; SRR, STrR, SHR: 2016 Medicare claims; Kt/V: 2016 CROWNWeb; Hypercalcemia: 2016 CROWNWeb; NHSN: 2016 CDC, ICH CAHPS: CMS 2015 and 2016.

In previous rulemaking, we have finalized that if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than they were for that measure in the previous year of the ESRD QIP, then we would substitute the previous year's performance standard, achievement threshold, and/or benchmark for that measure. In the CY 2017 ESRD PPS final rule, we finalized an update to that policy because in certain cases, it may be appropriate to re-baseline the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, such that expected infection rates are calculated on the basis of a more recent year's data (81 FR 77886). In such cases, numerical values assigned to performance standards may appear to decline, even though they represent higher standards for infection prevention. For PY 2021 and future payment years, we propose to continue use of this policy for the reasons explained above.

3. Proposed Change to the Scoring Methodology Previously Finalized for the PY 2021 ESRD QIP

As described in section IV.A.1 of this proposed rule, CMS has established the Meaningful Measures Initiative to help

guide and focus measure development efforts across settings. In order to align the ESRD QIP more closely with the priorities of that initiative, we proposed in section IV.B.1.c of this proposed rule to remove four reporting measures from the ESRD QIP measure set, beginning with PY 2021. In this section, we are proposing to make changes to the measure domains and weights.

a. Proposed Revision To Measure Domains Beginning With the PY 2021 ESRD QIP

To more closely align with the Meaningful Measures Initiative, we are proposing to eliminate the Reporting Domain and to reorganize the Clinical Domain into three distinct domains: Patient & Family Engagement Domain (currently part of the Patient and Family Engagement/Care Coordination Subdomain), Care Coordination Domain (currently part of the Patient and Family Engagement/Care Coordination Subdomain), and Clinical Care Domain (currently the Clinical Care Subdomain). Adopting these topics as separate domains would result in a measure set that is more closely aligned with the priority areas in the Meaningful Measures Initiative. The proposed Clinical Care Domain would align with the Meaningful Measure Initiative priority to promote effective prevention and treatment of chronic disease. The proposed Patient & Family Engagement Domain would align with the Meaningful Measures Initiative priority to strengthen person and family engagement as partners in their care. The proposed Care Coordination Domain would align with the Meaningful Measures Initiative priority to promote effective communication and coordination of care. We are also proposing to continue use of the Patient Safety Domain. The Patient Safety Domain would align with the Meaningful Measures Initiative priority to make care safer by reducing harm caused in the delivery of care. We are also proposing to eliminate the Reporting Measure Domain from the ESRD QIP measure set, beginning in the PY 2021 Program, because there would no longer be any measures in that domain if our measure removal proposals in section IV.B.1.c of this proposed rule and our proposals in section IV.B.3.b of this proposed rule to reassign the Ultrafiltration Rate, and Clinical Depression Screening and Follow-Up Reporting measures to the Clinical Care Measure Domain and the Care Coordination Measure Domain, respectively, are finalized.

b. Proposed Revisions to the PY 2021 Domain and Measure Weights Used To Calculate the Total Performance Score (TPS)

We are proposing to update the domain weights to reflect our proposed removal of the Reporting Domain and our proposed reorganization of the Clinical Domain into three distinct domains, as shown in Table 15. We believe that this proposed domain weighting best aligns the ESRD QIP's measure set with our preferred emphasis on clinical outcomes by assigning the two largest weights in the Program to the domains most focused on clinical outcomes (Clinical Care Domain and the Care Coordination Domain). Of those two domains, we are proposing to assign the Clinical Care Domain the highest weight because it contains the largest number of measures. We are proposing to assign the remaining two domains a smaller share of the total performance score (TPS) (both 15 percent) because they are more focused on measures of clinical processes and less on measures of patient outcomes. We continue to believe that the measures in the Patient & Family Engagement and Safety domains address important clinical topics, but we have concluded that placing more weighting on measures more directly tied to clinical outcomes is the most appropriate method to structure the ESRD QIP's measure domains.

We are also proposing to adjust the PY 2021 measure weights that were finalized in the CY 2018 ESRD PPS final rule (82 FR 50781 through 50783), as shown in Table 15. This proposal is also intended to reflect our preferred emphasis on weighting measures that directly impact clinical outcomes more heavily. We also took into consideration the degree to which a facility can influence a measure rate by assigning a higher weight to measures where a facility has greater influence compared to measures where a facility has less influence.

TABLE 15—PROPOSED DOMAIN AND MEASURE WEIGHTING FOR THE PY 2021 ESRD QIP

Proposed measures/ measure topics by domain	Proposed measure weight as percent of TPS
Patient & Family Engagement Measure Domain:	
ICH CAHPS measure	15.00
.	15.00
Care Coordination Measure Domain:	
SRR measure	14.00
SHR measure	14.00
Clinical Depression and Follow-Up reporting measure	2.00
	30
Clinical Care Measure Domain:	
Kt/V Dialysis Adequacy Comprehensive measure	6.00
Vascular Access Type measure topic*	6.00
Hypercalcemia measure	3.00
STrR measure	22.00
Ultrafiltration Rate reporting measure	3.00
	40
Safety Measure Domain:	
NHSN BSI measure	9.00
NHSN Dialysis Event reporting measure	6.00
	15

*The VAT Measure Topic is weighted for each facility based on the number of eligible patients for each of the two measures in the topic, with each measure score multiplied by the respective percentage of patients within the topic to reach a weighted topic score that will be unique for each facility (76 FR 70265, 70275).

As shown in Table 15, we are proposing to decrease the weight of the following measures: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) measure (18.75 to 15 percent), Kt/V Dialysis Adequacy Comprehensive measure (13.5 to 6 percent), and Vascular Access Type (VAT) measure topic (13.5 to 6 percent). We are also proposing to increase the weights of the following measures: Standardized Readmission Ratio (SRR) measure (11.25 to 14 percent), Standardized Hospitalization Ratio (SHR) measure (8.25 to 14 percent), Clinical Depression and Follow-Up measure (1.66 to 2 percent), Hypercalcemia measure (1.5 to 3 percent), STrR measure (8.25 to 22 percent), and Ultrafiltration reporting measure (1.66 to 3 percent). We are proposing these changes to reflect our continued evaluation of the ESRD QIP's measures and their contribution to the TPS in light of the proposed domain structure and weights as well as the proposed removal of the four reporting

measures. We note that we are not proposing any changes to the two measures included in the Safety Measure Domain: NHSN BSI and NSHN Dialysis Event measures. We continue to believe that the Safety domain appropriately contains these two NHSN measures and we believe their assigned weights—9 percent and 6 percent respectively—reflect the importance that we place on measures of patient safety for the PY 2021 ESRD QIP.

We seek comment on our proposed domain and measure weighting proposals.

Proposals To Update the Eligibility Requirement for Receiving a TPS for a PY and Reassign Measure Weights

In the CY 2017 ESRD PPS final rule (81 FR 77888 through 77889), we finalized that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Domain. We are proposing to revise this policy due to our proposed removal of the Reporting Domain from the ESRD QIP measure set and our proposal to increase the number of domains overall from three to four. We are proposing that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in any two out of the four domains in the ESRD QIP measure set. The proposed approach is consistent with our previously finalized policy because it would allow facilities to receive a TPS with as few as two measure scores. The proposed approach also enables us to maximize the number of facilities that can participate, while ensuring that ESRD facilities are scored on a sufficient number of measures to create a sufficiently-reliable TPS.

Because of this proposed eligibility requirement to receive a TPS, we concluded that we must also consider how to reassign measure weights in those cases where facilities do not receive a score on every measure but receive scores on enough measures to receive a TPS. We considered two alternatives to address this issue: (1) Redistribute the weights of missing measures evenly across the remaining measures (that is, we would divide up the missing measure weights equally across the remaining measures), and (2) redistribute the weights of missing measures proportionately across the remaining measures, based on their weights as a percentage of TPS (that is, when dividing up missing measure weights, we would shift a larger share of the weights to measures with higher assigned weights; measures with lower weights would gain a smaller portion of the missing measure weights).

While the first policy alternative is administratively simpler to implement, this option would not maintain the Meaningful Measures Initiative priorities in the measure weights as effectively, and therefore, we are proposing the second policy alternative. As discussed earlier, we are proposing an approach for reweighting the domains and measures in the ESRD QIP for PY 2021 based on the priorities identified in the Meaningful Measures Initiative. Under this approach, we are proposing to assign a higher weight to measures that focus on outcomes and a lower weight to measures that focus on clinical processes. If we adopted the first policy alternative, measures that we consider a lower priority would represent a much larger share of TPS relative to measures that we consider a higher priority, in situations where a facility is missing one or more measure scores. Under the second policy alternative, when a facility is not scored on a measure, the weight of lower priority measures relative to higher priority measures would be more consistent with the weights assigned to the complete measure set. We note that this proposal, if finalized, would be effective for PY 2021; we use the PY 2022 measure set for the following example. If a facility was ineligible to receive a score on all of the measures in both the Clinical Care Measure Domain and the Safety Measure Domain in PY 2022, the weight of the Clinical Depression and Follow-Up Measure—the lowest weighted measure remaining in the measure set would increase from 2.5 percent of the TPS to 13.5 percent of the TPS under the first policy alternative and would increase from 2.5 percent of the TPS to 5.6 percent of the TPS under the second policy alternative. Under the same scenario, the weight of the ICH CAHPS measure—the highest weighted remaining in the measure set would increase from 15 percent to 26 percent under the first policy alternative and would increase from 15 percent to 33.33 percent under the second policy alternative.

Therefore, based on these considerations, we are proposing that in cases where a facility does not receive a score on one or more measures but receives scores on enough measures to receive a TPS, we would redistribute the weights of any measures for which the facility does not receive a score to the remaining measures proportionately based on their measures weight as a percent of the TPS. This redistribution would occur across all measures, regardless of their domain, and would be effective beginning PY 2021. We have concluded that this policy would more effectively maintain the Meaningful Measure Initiative's priorities in the ESRD QIP's measure weights in situations where a facility does not receive a score on one or more measures. We believe that this proportional reweighting would ensure ESRD QIP TPSs are calculated in a fair and equitable manner.

We seek comment on this proposal.

4. Proposed Update to the Requirement To Begin Reporting Data for the ESRD QIP

In the CY 2013 ESRD PPS final rule, we finalized our current policy to begin counting the number of months in which a facility is open on the first day of the month after the facility's CMS Certification Number (CCN) Open Date (77 FR 67512 through 67513). In response to comments suggesting that facilities be required to begin reporting on the first day of the third month after its CCN Open Date, we agreed that a facility needs time to ensure that its systems are in place to report the data, and we adopted policies that would allow new facilities to be exempted from scoring on individual measures based on their CCN Open Date. Despite these policies, we have continued to receive feedback that new facilities need additional time to deploy their information systems and enroll in CROWNWeb and NHSN. This feedback was presented both through the rulemaking process (80 FR 69066), and during the period in which facilities preview their scores. In response to this continued feedback, we have taken another look at our eligibility policies for new facilities, keeping in mind that program requirements have become more complex over time, and have concluded that our existing policy may not provide new facilities with sufficient time to enroll in CROWNWeb and the NHSN, or otherwise prepare to report the data needed for the ESRD QIP.

Accordingly, for PY 2021 and beyond, we are proposing to update this policy. The proposed policy would require facilities to collect data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CCN becomes effective. For example, if a facility has a CCN effective date of January 15, 2019, that facility would be required to begin collecting data for purposes of the ESRD QIP beginning with services furnished on May 1, 2019. The proposed policy would provide facilities with a longer time period than they are given now to

become familiar with the processes for collecting and reporting ESRD QIP data before those data are used for purposes of scoring. We believe this policy appropriately balances our desire to incentivize prompt participation in the ESRD QIP with the practical challenges facing new ESRD facilities as they begin operations.

We welcome public comments on this proposal.

5. Estimated Payment Reduction for the PY 2021 ESRD QIP

Under our current policy, a facility will not receive a payment reduction in connection with its performance under the PY 2021 ESRD QIP if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (1) It performs at the performance standard for each clinical measure; and (2) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2019 reporting measures (82 FR 50787 through 50788).

We were unable to calculate a minimum a TPS for PY 2021 in the CY 2018 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated in the CY 2018 ESRD PPS final rule (82 FR 50787 through 50788) that we would publish the minimum TPS for the PY 2021 ESRD QIP in the CY 2019 ESRD PPS final rule.

Based on the estimated performance standards proposed in section IV.B.2 of this proposed rule, we estimate that a facility must meet or exceed a minimum TPS of 57 for PY 2021. For all of the clinical measures, these data come from CY 2017. We are proposing that a facility that achieves a TPS below the minimum TPS that we set for PY 2021 would receive payment reduction based on the estimated TPS ranges indicated in Table 16.

TABLE 16—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2021 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–57	0
56–47	0.5
46–37	1.0
36–27	1.5
26–0	2.0

We intend to finalize the minimum TPS for PY 2021, as well as the payment reduction ranges for that PY, in the CY 2019 ESRD PPS final rule.

We see comment on these proposals.

6. Data Validation Proposals for PY 2021 and Subsequent Years

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: The CROWNWeb pilot data validation study (OMB Control Number 0938–1289) and the NHSN dialysis event validation study (OMB Control Number 0938–1340).

Since the PY 2016 ESRD QIP, we have validated data submitted to CROWNWeb for each payment year by sampling no more than 10 records from 300 randomly selected facilities (78 FR 72223 through 72224). In the CY 2018 ESRD PPS final rule, we finalized that for PY 2020, we would continue validating these data using the same methodology, but also finalized that we would deduct 10 points from a facility's TPS for PY 2020 if the facility was selected for validation but did not submit the requested records within 60 calendar days of receiving a request (82 FR 50766 through 50767).

Since we issued the CY 2018 ESRD PPS final rule, we have considered whether it is appropriate to continue to refer to this validation of CROWNWeb data as a study. We analyzed the CROWNWeb data that we used for purposes of the PY 2016 validation study to determine how reliable the current methodology is, and our analysis showed an overall match rate of 92.2 percent among the facilities selected for participation. Additionally, based on our statistical analyses, we have concluded that the validation study is well-powered when we sample 10 records per facility from 300 facilities, meaning that a validation study implemented with those sampling requirements will meet our needs when assessing the accuracy and completeness of facilities' CROWNWeb data submissions.

This analysis indicates that our validation methodology produces reliable results and can be used to ensure that accurate ESRD QIP data are reported to CROWNWeb. Therefore, we are proposing to validate the CROWNWeb data submitted for the ESRD QIP, beginning with CY 2019 data submitted for PY 2021, using the methodology we first adopted for the PY 2016 ESRD QIP and updated for the PY 2020 ESRD QIP. Under this methodology, we would sample no more than 10 records from 300 randomly selected facilities each year, and we would deduct 10 points from a facility's TPS if the facility was selected for validation but did not submit the requested records.

With respect to data submitted to the NSHN, we have been developing and testing a protocol for validating those data on a statistically relevant scale. For PY 2020, our methodology for this feasibility study is to randomly select 35 facilities and require that each of those facilities submit 10 patient records covering 2 quarters of data reported in CY 2018. Our selection process targets facilities for NHSN validation by identifying which facilities that are at risk for under-reporting. For additional information on this methodology, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

We have continued to work with the Centers for Disease Control and Prevention (CDC) to determine the most appropriate sample size for achieving reliable validation results through this NSHN dialysis event validation study. Based on recent statistical analyses conducted by the CDC, we have concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities. This sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on these results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP is accurate, we are proposing to increase the sample sizes used for the NHSN dialysis event validation study, over a 2 year period, to 300 facilities and 20 records per quarter for each of the first 2 quarters of the CY for each facility selected to participate in the study.

Specifically, for PY 2021, we are proposing to increase the number of facilities that we would select for validation to 150, and then for PY 2022, to increase that number to 300. With respect to the number of patient records that each selected facility would be required to submit to avoid a 10 point deduction to its TPS for that payment year, we are proposing that for both PY 2021 and PY 2022, each selected facility must submit 20 patient records per quarter for each of the first 2 quarters of the CY, within 60 calendar days of receiving a request. We are also proposing to continue targeted validation.

We seek comments on these proposals. We also seek comments on potential future policy proposals that would encourage accurate, comprehensive reporting to the NHSN, such as introducing a penalty for facilities that do not meet an established reporting or data accuracy threshold,

introducing a bonus for facilities that perform above an established reporting or data accuracy threshold, developing targeted education on NHSN reporting, or requiring that a facility selected for validation that does not meet an established reporting or data accuracy threshold be selected again the next year.

C. Proposed Requirements for the PY 2022 ESRD QIP

1. Proposed Continuing and New Measures for the PY 2022 ESRD QIP

If our proposal to remove four measures beginning with the PY 2021 ESRD QIP is finalized, the PY 2021 ESRD QIP measure set would have 12 measures. In the CY 2013 ESRD PPS final rule, we finalized that once a quality measure is selected and finalized for the ESRD QIP through rulemaking, the measure would continue to remain part of the Program for all future years, unless we remove or replace it through rulemaking or notification (if the measure raises potential safety concerns) (77 FR 67475). In addition to continuing all of the measures included in the PY 2021 ESRD QIP, we are proposing to adopt two new measures beginning with the PY 2022 ESRD QIP: Percentage of Prevalent Patients Waitlisted clinical measure and the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities reporting measure.

a. Proposed Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure

We are proposing to add one new transplant clinical measure to the ESRD QIP measure set beginning with PY 2022: (1) Percentage of Prevalent Patients Waitlisted (PPPW). The proposed new PPPW measure would align the ESRD QIP more closely with a Meaningful Measures Initiative priority area—increased focus on effective communication and coordination. The proposed measure assesses the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist.

Background

The benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD are well established. Although no clinical trials comparing the two have ever been done due to ethical considerations, a large number of observational studies have been conducted demonstrating improved survival and quality of life with kidney transplantation.[11] Despite the benefits of kidney transplantation, the total number of transplants performed in the U.S. has stagnated since 2006.[12] There is also wide variability in transplant rates across ESRD networks.[13] Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, a measure to encourage facilities to coordinate care with transplant centers to waitlist patients is warranted.

This measure emphasizes shared accountability between dialysis facilities and transplant centers.

Data Sources

The proposed PPPW measure uses CROWNWeb data to calculate the denominator, including the risk adjustment and exclusions. The Organ Procurement and Transplant Network (OPTN) is the data source for the numerator (patients who are waitlisted.) The OPTN is a public-private partnership established by the National Organ Transplant Act in 1984. The private nonprofit organization, United Network for Organ Sharing (UNOS) handles administration of the waitlist under a contract with the federal government. The Nursing Home Minimum Dataset and Questions 17u and 22 on the Medical Evidence Form CMS–2728 are used to identify ESRD patients who were admitted to a skilled nursing facility (SNF) because those patients are excluded from the measure. A separate CMS file that contains final action claims submitted by hospice providers is used to identify ESRD patients who have been admitted to hospice because those patients are also excluded from the measure.

Outcome

The PPPW measure tracks the percentage of patients attributed to each dialysis facility during a 12-month period who were on the kidney or kidney-pancreas transplant waitlist. The measure is a directly standardized percentage, in that each facility's percentage of kidney transplant patients on the kidney transplant waitlist is based on the number of patients one would expect to be waitlisted for a facility with patients of similar age and co-morbidities.

Cohort

The PPPW measure includes ESRD patients who are under the age of 75 on the last day of each month and who are attributed to the dialysis facility. We create a treatment history file using a combination of Medicare dialysis claims, the Medical Evidence Form CMS–2728, and data from CROWNWeb as the data source for the facility attribution. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or until the measurement period ends. For each patient, a new record is created each time he or she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. Each patient-month is assigned to only one facility. A patient could be counted up to 12 times in a 12-month reporting period, and home dialysis is included.

Inclusion and Exclusion Criteria

The PPPW measure excludes patients 75 years of age or older on the last day of each month. Additionally, patients who are admitted to a SNF or hospice during on the date that the monthly count takes place are excluded from the denominator for that month. An eligible monthly patient count takes place on the last day of each month during the performance period.

Risk Adjustment

The PPPW measure is adjusted for patient age. The measure is a directly standardized percentage, in the sense that each facility's percentage of patients on the waitlist is adjusted to the national age distribution. Further information on the risk adjustment model can be found in the PPPW Methodology Report (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*). We assume a logistic regression model for the probability that a prevalent patient is waitlisted.

2017 Measures Application Partnership Review

We submitted the PPPW measure to the Measures Application Partnership in 2017 for consideration as part of the pre-rulemaking process, and Measures Application Partnership's final

[11] Tonelli M, Wiebe N, Knoll G, et al. Systematic review: Kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplantation 2011 Oct; 11(10): 2093–2109.

[12] Schold JD, Buccini LD, Goldfarb DA, et al. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. Clin J Am Soc Nephrol. 2014 Oct 7; 9(10):1773–80.

[13] Patzer RE, Plantinga L, Krisher J, Pastan SO. *Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities.* Am J Transplant. 2014 Jul; 14(7):1562–72.

recommendations may be found at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*.

The Measures Application Partnership expressed conditional support for the PPPW measure for inclusion in the ESRD QIP. The Measures Application Partnership acknowledged that the measure addresses an important quality gap in dialysis facilities, but discussed a number of factors that it believed should be balanced when implementing the measure. The Measures Application Partnership reiterated the critical need to help patients receive kidney transplants to improve their quality of life and reduce their risk of mortality. The Measures Application Partnership also noted that there are disparities in the receipt of kidney transplants and there is a need to incentivize dialysis facilities to educate patients about waitlisting processes and requirements. The Measures Application Partnership also acknowledged that a patient's suitability to be waitlisted may not be within the control of a dialysis facility or transplant centers. The Measures Application Partnership also noted the need to ensure that the measure is appropriately risk-adjusted and recommended that CMS explore whether it would be appropriate to adjustment the measure for social risk factors and proper risk model performance. The Measures Application Partnership conditionally supported the measure with the condition that CMS submit it to the NQF for consideration of endorsement. Specifically, the Measures Application Partnership recommended that this measure be reviewed by NQF's Scientific Methods Panel as well the Renal Standing Committee. The Measures Application Partnership recommended that as part of the endorsement process, the NQF examine the validity of the measure, particularly the risk adjustment model and if it appropriately accounts for social risk. Finally, the Measures Application Partnership noted the need for the Disparities Standing Committee to provide guidance on potential health equity concerns.

In response to these recommendations, we have submitted the measure to the NQF for consideration of endorsement, and our understanding is that it will be evaluated by all of the committees that the Measures Application Partnership suggested. We note further that access to transplantation is a known area of disparity and has a known performance gap, and the Measures Application Partnership coordinating committee expressed strong support for the measure.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to Measures Application Partnership's website at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*.

Based on the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD, and taking into account the Measures Application Partnership's conditional endorsement and our submission of the measure to the NQF for consideration of endorsement, we propose to adopt the PPPW measure beginning with the PY 2022 ESRD QIP. We note also that there are currently no NQF-endorsed transplant measures that we could have considered, and that we believe we should adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We welcome comments on this proposal.

b. Proposed New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Reporting Measure

We are proposing to adopt the New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure for the ESRD QIP measure set, beginning with PY 2022. The MedRec measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the ESRD patient population because those patients typically take a large number of medications. Inclusion of the MedRec measure in the ESRD QIP measure set would align with the Meaningful Measure Initiative priority area of making care safer by reducing harm caused by care delivery.

Medication management is a critical safety issue for all patients, but especially for patients with ESRD, who are often prescribed 10 or more medications simultaneously, take an average of 17 to 25 doses per day, have numerous comorbid conditions, have multiple healthcare providers and prescribers, and undergo frequent medication regimen changes.[14] Medication-related problems contribute significantly to the approximately $40 billion in public and private funds spent annually on ESRD care in the U.S.; for patients with chronic kidney disease alone, this figure is $10 billion.[15] We believe that medication management practices focusing on medication documentation, review, and reconciliation could systematically identify and resolve medication-related problems, improve ESRD patient outcomes, and reduce total costs of care.

Data Sources

The proposed MedRec measure is calculated using administrative claims and electronic clinical data from CROWNWeb, and facility medical records. For additional information on the measure, we refer readers to the measure steward's website; the Kidney Care Quality Alliance (KCQA): *http://kidneycarepartners.com/wp-content/uploads/2014/11/tbKCQA_NQF endorsedSpecs10-26-17.pdf*. The KCQA is funded by Kidney Care Partners (KCP), a coalition of patient advocates, dialysis professionals, care providers, and manufacturers, and was established in 2005 as an independent organization for the purpose of developing quality measures for use in the dialysis setting of care.

Outcome

The outcome of the MedRec measure is the provision of medication reconciliation services and their documentation by an eligible professional for patients attributed to dialysis facilities each month.

Cohort

The MedRec measure includes all patients attributed to a dialysis facility during each month of the performance period. The numerator is the number of patient-months for which medication reconciliation was performed and documented by an eligible professional during the reporting period. The denominator statement is the total number of eligible patient-months for all patients attributed to a dialysis facility during the reporting period.

Inclusion and Exclusion Criteria

The MedRec measure excludes in-center patients who receive less than 7 hemodialysis treatments in the facility during the reporting month.

Risk Adjustment

The MedRec measure is not risk-adjusted because it is process measure.

[14] Cardone KE, Bacchus S, Assimon MM, Pai AB, Manley HJ. Medication-related problems in CKD. Adv Chronic Kidney Dis. 2010;17(5):404–412.

[15] Parker WM and Cardone KE. Medication Management Services in a Dialysis Center: Patient and Dialysis Staff Perspectives. Albany College of Pharmacy and Health Services. January 2015. Available at: *http://www.acphs.edu*. Accessed March 22, 2016.

2017 Measures Application Partnership Review

We submitted the MedRec measure to the Measures Application Partnership in 2017 for consideration as part of the pre-rulemaking process, and the Measures Application Partnership addressed the measure in its February 2018 Hospital Workgroup report.[16] The Measures Application Partnership supported the measure for the ESRD QIP, noting that the measure is NQF-endorsed and addresses both patient safety and care coordination. The Measures Application Partnership also noted that the topic of medication reconciliation is currently a gap area in the ESRD QIP's measure set and that the measure has broad support across stakeholders. The Measures Application Partnership emphasized that medication reconciliation is an important issue for ESRD patients who see multiple clinicians and may require numerous medications. The Measures Application Partnership noted that administration of the wrong medication can have grave consequences for an ESRD patient.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to the Measures Application Partnership's website at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

We agree with the Measures Application Partnership's assessment that the MedRec measure is appropriate for the ESRD QIP because medication reconciliation is currently a gap area in the Program's measure set and is an important issue for ESRD patients who receive care from multiple clinicians and providers and may require numerous medications. ESRD patients can be significantly harmed by medication administration errors. We continue to believe that care coordination is a critical quality improvement topic. We therefore, propose to adopt the MedRec measure beginning with the PY 2022 ESRD QIP and to place the measure into the Patient Safety Domain. We note further that, as required by section 1881(h)(2)(B)(i) of the Act, CMS is required to use endorsed measures in the ESRD QIP unless the exception at section 1881(h)(2)(B)(ii) of the Act applies. The MedRec measure is endorsed by NQF as #2988.

[16] Available at: *https://www.qualityforum.org/Publications/2018/02/2018_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx*.

2. Proposed Performance Period for the PY 2022 ESRD QIP

We propose to establish CY 2020 as the performance period for the PY 2022 ESRD QIP for all measures. We continue to believe that a 12-month performance period provides us sufficiently reliable quality measure data for the ESRD QIP.

We welcome comment on this proposal.

3. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2022 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act provides that ''the Secretary shall establish performance standards with respect to measures elected . . . for a performance period with respect to a year.'' Section 1881(h)(4)(B) of the Social Security Act (the Act) further provides that the ''performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary.'' We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for Clinical Measures in the PY 2022 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we are proposing for PY 2022 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures (including the proposed PPPW measure) at the 50th, 15th, and 90th percentile, respectively, of the national performance in CY 2018. We are also proposing to apply these performance standards to all clinical measures we use for the ESRD QIP in future payment years. We welcome comment on these proposals.

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures because we do not yet have data from CY 2018 or the first period of CY 2019. We intend to publish these numerical values, using data from CY 2018 and the first portion of CY 2019, in the CY 2019 ESRD PPS final rule.

b. Proposed Performance Standards for the PY 2022 Reporting Measures

In the CY 2016 ESRD PPS final rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up reporting measure (79 FR 66209). In the CY 2017 ESRD PPS final rule, we finalized performance standards for the Ultrafiltration Rate reporting measure (81 FR 77916) and the NHSN Dialysis Event reporting measure (81 FR 77916). We propose to continue use of these performance standards for these reporting measures for the PY 2022 and future payment years.

For the proposed MedRec reporting measure, we propose to set the performance standard for PY 2022 and future payment years as successfully reporting the following data elements for the measure to CROWNWeb, for each qualifying patient, on a monthly basis, during the performance period: (1) The date that the facility completed the medication reconciliation, (2) the type of clinician who completed the medication reconciliation, and (3) the name of the clinician.

We welcome comments on these proposals.

4. Proposals for Scoring the PY 2022 ESRD QIP and Subsequent Years

a. Proposal To Score Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). We propose to use this methodology for scoring achievement for each clinical measure, including the proposed PPPW measure, for the PY 2022 ESRD QIP and for future program years.

b. Proposal To Score Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). For the PY 2022 ESRD QIP, we propose to continue that policy, defining the improvement threshold as the facility's performance on the measure during the baseline period (which for PY 2022, would be CY 2019). The facility's improvement score would be calculated by comparing its performance on the measure during CY 2020 (the proposed performance period) to the improvement threshold and benchmark. We also propose to use this same methodology for scoring the PPPW measure proposed in section IV.C.1.a of this proposed rule. Finally, we propose to continue this policy for subsequent years of the ESRD QIP.

c. Scoring Facility Performance on Reporting Measures

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression

Screening and Follow-Up reporting measures in the ESRD QIP (79 FR 66210 through 66211). In the CY 2017 ESRD PPS final rule, we finalized policies for scoring performance on the Ultrafiltration Rate reporting measure (81 FR 77917). We propose to continue use of these policies for the two continuing reporting measures for the PY 2022 ESRD QIP and subsequent years.

For the PY 2022 ESRD QIP, we propose to score facilities with a CCN Open Date before January 1st of the performance period year (which, for the PY 2022 ESRD QIP, would be 2020) on the proposed MedRec measure using a formula similar to the one previously finalized for the Ultrafiltration Rate reporting measure (81 FR 77917):

((# patient-months successfully reporting data)/(# eligible patient-months)*12)–2)

As with the Ultrafiltration Rate reporting measure, we would round the result of this formula (with half rounded up) to generate a measure score from 0–10. We also propose to score facilities using this methodology for subsequent years of the ESRD QIP.

We welcome public comment on all of these scoring proposals.

d. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). We are proposing to use this scoring methodology for the PY 2022 ESRD QIP and subsequent years.

We welcome comments on this scoring proposal.

5. Proposals for Weighting the Measure Domains, and for Weighting the TPS for PY 2022

For PY 2022, we are proposing to continue use of the domain weights proposed for PY 2021 in section IV.B.3 of this proposed rule, and to update the individual measure weights in the Care Coordination Domain and Safety Domain to reflect the introduction of one new proposed measure in each of those domains. We are proposing to assign the proposed PPPW measure to the Care Coordination Domain, with a weight of 4 percent of the TPS. To accommodate the addition of the PPPW measure to the Care Coordination Domain without having to adjust the domain's overall weight, we are proposing to reduce the weight of two continuing measures in the Care Coordination Domain as follows: The SRR measure from 14 to 12 percent and the SHR measure from 14 to 12 percent. We are proposing to assign the proposed MedRec measure to the Safety Domain, with a weight of 4 percent of the TPS (see Table 17). To accommodate the addition of the new MedRec measure to the Safety Domain without having to adjust the domain's overall weight, we are proposing to reduce the weight of two continuing measures in the Safety Domain as follows: The NHSN BSI clinical measure from 9 to 8 percent and the NHSN Dialysis Event measure from 6 to 3 percent. To assign these proposed measure weights, we used the same rationale as proposed for PY 2021.

TABLE 17—PROPOSED REVISIONS TO MEASURE WEIGHTS FOR THE PY 2022 ESRD QIP

Measures/measure topics by subdomain	Measure weight within the domain (proposed for PY 2022)	Measure weight as percent of TPS (proposed for PY 2022)
CARE COORDINATION MEASURE DOMAIN		
SRR measure	40.00%	12.00%.
SHR measure	40.00	12.00.
PPPW measure	13.33	4.00.
Clinical Depression and Follow-Up reporting measure	6.67	2.00.
TOTAL: CARE COORDINATION MEASURE DOMAIN	100% of Care Coordination Measure Domain.	30% of TPS.
SAFETY MEASURE DOMAIN		
MedRec measure	26.67	4.00.
NHSN BSI clinical measure	53.33	8.00.
NHSN Dialysis Event reporting measure	20.00	3.00.
TOTAL: SAFETY MEASURE DOMAIN	100% of Safety Measure Domain.	15% of TPS.

In section IV.B.3.b of this proposed rule, we propose that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in two of the four measure domains. If that proposal is finalized, we would apply it to PY 2022 and subsequent payment years.

We seek comments on these proposals.

6. Eligibility Proposals for the PY 2022 ESRD QIP and Subsequent Payment Years

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period (77 FR 67510 through 67512). We propose to continue use of these minimum data policies for the PY 2022 ESRD QIP measure set and in subsequent years. We are also proposing to use these same minimum data policies for the proposed PPPW measure and proposed MedRec measure for the PY 2022 ESRD QIP and subsequent years.

We seek comment on these proposals.

7. Payment Reductions for the PY 2022 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. For additional information on payment reduction policies, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50787 through 50788).

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. In the CY 2020 ESRD PPS proposed rule, we will propose the minimum TPS, based on CY 2018 data.

D. Proposed Requirements Beginning With the PY 2024 ESRD QIP

1. Proposed New Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients Clinical Measure

We are proposing to add one new transplant measure to the ESRD QIP measure set beginning with PY 2024: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR). The proposed new SWR measure would align the ESRD QIP more closely with the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The SWR Measure assesses the number of patients who are placed on the transplant waitlist or receive a living donor kidney within one year of the date when dialysis is initiated. We believe this measure would encourage facilities to more rapidly evaluate patients for transplant and coordinate the waitlisting of those patients.[17] Because the proposed SWR measure is limited to patients in their first year of dialysis, it is more limited in scope than the proposed PPPW measure, which includes patients who have been on dialysis for longer than 1 year. We are proposing to introduce the SWR measure for PY 2024 rather than PY 2022 because the proposed SWR measure is calculated using 3 years of data.

Data Sources

The SWR Measure is calculated using administrative claims and electronic clinical data. CROWNWeb is the primary source used to attribute patients to dialysis facilities and dialysis claims are used as an additional source. Information regarding onset of ESRD, the first ESRD treatment date, death, and transplant is obtained from CROWNWeb (including the Medical Evidence Form CMS–2728 and the Death Notification Form CMS–2746) and Medicare claims, as well as the Organ Procurement and Transplant Network.

Outcome

The SWR Measure tracks the number of incident patients attributed to the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis. Similar to the PPPW measure, the SWR measure emphasizes shared accountability between dialysis facilities and transplant centers.

Cohort

The SWR measure includes patients under the age of 75 and attributed to the dialysis facility using CROWNWeb data and Medicare claims who are listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis. Patients are attributed to the dialysis facility listed on the Medical Evidence Form CMS–2728.

Inclusion and Exclusion Criteria

The SWR measure excludes patients at the facility who were 75 years of age or older at initiation of dialysis and patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis. Additionally, patients who are admitted to a SNF or hospice at the time of initiation of dialysis are excluded.

Risk Adjustment

The SWR measure is adjusted for incident comorbidities and age. Incident comorbidities were selected for adjustment into the SWR model based on demonstration of a higher associated mortality (hazard ratio above 1.0) and statistical significance (p-value in first year mortality model). More details about the risk adjustment model can be found in the SWR Methodology Report (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*).

2017 Measures Application Partnership Review

We submitted the SWR measure to the Measures Application Partnership in 2017 for consideration as part of the pre-rulemaking process.

In its report (available on its website at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*), the Measures Application Partnership acknowledged that the SWR measure addresses an important quality gap for dialysis facilities and discussed a number of factors that it believed should be balanced when implementing the measure. The Measures Application Partnership reiterated the critical need to help patients receive kidney transplants to improve their quality of life and reduce their risk of mortality. The Measures Application Partnership also noted there are disparities in the receipt of kidney transplants and there is a need to incentivize dialysis facilities to educate patients about waitlist processes and requirements. The Measures Application Partnership also acknowledged concerns and public comment about the locus of control of the measure, where dialysis facilities may not be able to as adequately influence a patient's suitability to be waitlisted as well as the transplant center. The Measures Application Partnership also noted the need to ensure the measure is appropriately risk-adjusted and recommended the exploration of adjustment for social risk factors and proper risk model performance. The Measures Application Partnership ultimately conditionally supported the measure with the condition that it is submitted for NQF review and endorsement. Specifically, the Measures Application Partnership recommended that this measure be reviewed by the NQF Scientific Methods Panel as well the Renal Standing Committee. The Measures Application Partnership recommended the endorsement process examine the validity of the measure, particularly the risk adjustment model and if it appropriately accounts for social risk. Finally, the Measures Application Partnership noted the need for the Disparities Standing Committee to provide guidance on potential health equity concerns. Our understanding is that the NQF endorsement process covers all of the Measure Application Partnership's conditions, and we have submitted the measure for endorsement.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to Measures Application Partnership's website at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*.

Based on the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD, and taking into account the Measures Application Partnership's conditional endorsement and our submission of the measure for NQF endorsement, we propose to adopt the SWR measure beginning with the PY 2024 ESRD QIP. We also propose to place this measure in the Transplant Waitlist measure topic in the Care Coordination Domain, along with the PPPW measure proposed in section IV.C.1.a of this proposed rule, and to score the two measures accordingly as a measure topic. We note also that there are currently no NQF-endorsed

[17] Meier-Kriesche, Herwig-Ulf, and Bruce Kaplan. ''Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis1.'' Transplantation 74.10 (2002): 1377–1381; Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., Leichtman, A. B & Kaplan, B. (2000). Effect of waiting time on renal transplant outcome. Kidney international, 58(3), 1311–1317.

transplant measures that we could have considered, and we believe that we should adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We welcome comments on these proposals.

2. Proposed Performance Period for the SWR Measure

Because the SWR measure is calculated using 36 months of data, we propose to establish a 36-month performance period for the proposed SWR measure. With respect to PY 2024 ESRD QIP, this period would be CY 2019 through 2021. We believe that a 36-month performance period for the SWR measure would enable us to calculate sufficiently reliable measure data for the ESRD QIP.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the SWR Measure in the PY 2024 ESRD QIP

If our proposal in section IV.D.1 of this proposed rule is finalized, then we would score the proposed SWR measure using a 36-month performance period for purposes of achievement and a corresponding 36-month baseline period for purposes of improvement. For the PY 2024 ESRD QIP, these periods would be CY 2017 through 2019 for achievement and CY 2018 through 2020 for improvement.

At this time, we do not have the necessary data to assign numerical values to the performance standards for the SWR measure, because we do not yet have data from CY 2017 through CY 2020.

V. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

A. Background

Section 1847(a) of the Social Security Act (the Act), as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs in competitive bidding areas (CBAs) throughout the United States (U.S.) for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The competitive bidding programs of the Medicare Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP), mandated by section 1847(a) of the Act, are collectively referred to as ''DMEPOS CBP''. A final rule published on April 10, 2007 in the **Federal Register**, titled ''Competitive Acquisition for Certain DMEPOS and Other Issues'', (72 FR 17992), referred to as ''2007 DMEPOS final rule'', established competitive bidding programs for certain Medicare Part B covered items of DMEPOS throughout the U.S. The competitive bidding programs, which were phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services. Section 1847(a)(2) of the Act describes the items and services subject to the DMEPOS CBP:

- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act.
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act.
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DMEPOS CBP was modeled after successful demonstration programs from the late 1990s and early 2000s, discussed in the proposed rule published on May 1, 2006 in the **Federal Register**, titled ''Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'' (71 FR 25654) referred to as ''2006 DMEPOS proposed rule''. We received substantial advice in the development of the DMEPOS CBP from the Program Advisory and Oversight Committee (PAOC), which was mandated through section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, to establish a committee to provide advice to the Secretary with respect to the following functions:

- The implementation of the Medicare DMEPOS CBP.
- The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS CBP, taking into account the needs of small providers.
- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS CBP.
- The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.
- The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

As authorized under section 1847(c)(2) of the Act, the PAOC members were appointed by the Secretary of the Department of Health and Human Services (the Secretary) and represented a broad mix of relevant industry, consumer, and government parties. The representatives had expertise in a variety of subject matter areas, including DMEPOS, competitive bidding methodologies and processes, and rural and urban marketplace dynamics.

In the DMEPOS CBP, suppliers bid for contracts for furnishing multiple items and services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, under several different product categories. Section 1847(a)(1)(B) and (D) of the Act mandated the phase in of the DMEPOS CBP in nine of the largest MSAs (Round 1), followed by 91 additional large MSAs (Round 2), and finally in additional areas, which do not necessarily need to be tied to MSAs. Round 1 and Round 2 CBAs that included more than one state have been subdivided into state-specific CBAs. The CBP is currently operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the CBP has not yet been phased in, including approximately 275 MSAs. In addition, CMS phased in a national mail order program for diabetic testing supplies in 2013. In the Round 1 2017 and Round 2 Recompete competitions, the product categories currently include: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies; Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive pressure airway devices, and respiratory assist devices); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies. Since there are multiple items in each product category, a ''composite'' bid is calculated for each supplier to determine which supplier's bids would result in the greatest savings

to Medicare for the product category. A supplier's composite bid for a product category is calculated by multiplying a supplier's bid for each item in a product category by the item's weight and taking the sum of these numbers across items. The weight of an item is based on the annual utilization of the individual item compared to other items within that product category based on recent Medicare national claims data. Item weights are used to reflect the relative market importance of each item in the product category. Item weights ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier. The sum of each supplier's weighted bids for every item in a product category is the supplier's composite bid for that product category.

Each supplier submits a bid amount for each item in the product category, and multiple contracts must be awarded for each product category in each CBA. Section 1847(b)(5) of the Act mandates a single payment amount (SPA) for each item based on winning bids from multiple suppliers, so various options for calculating the SPA were addressed in the 2006 DMEPOS proposed rule (71 FR 25679). The methods of using the minimum winning bid amount for each item, the maximum winning bid amount for each item, the median of the winning bid amounts for each item, and an average adjusted price based on the method used during the demonstrations were considered during this rulemaking. The SPA calculation method using the median of the winning bids was finalized in the 2007 DMEPOS final rule (72 FR 18044) based on the rationale that the median of winning bids represents the bid amounts of the winning suppliers as a whole, whereas the minimum and maximum bids did not; it is a simpler method than the average adjusted price method; and it is consistent with the longstanding Medicare payment rules for DMEPOS that established allowed payment amounts based on average reasonable charges rather than minimum or maximum charges.

To implement section 522(a) of the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA), we published a final rule on November 4, 2016 in the **Federal Register**, titled ''End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model'' (81 FR 77834), referred to as ''2016 ESRD PPS final rule''.

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of MACRA, requires bidding entities to secure a bid surety bond by the deadline for bid submission. Section 1847(a)(1)(G) of the Act provides that, with respect to rounds of competitions under section 1847 of the Act beginning not earlier than January 1, 2017 and not later than January 1, 2019, a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of $50,000 to $100,000, in a form specified by the Secretary consistent with paragraph (H) of section 1847(a)(1) of the Act, and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s). We believe that section 522(a) of MACRA was drafted under the assumption that the next round of competitive bidding would have been implemented at some point between January 1, 2017 and January 1, 2019. We have interpreted section 522(a) of MACRA as applying to the next round of competitive bidding even though the next round of competition will begin after the time period specified in the statute. Section 1847(a)(1)(H)(i) of the Act provides that in the event that a bidding entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amount(s) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and the Secretary will collect on the bid surety bond(s). In instances where a bidding entity does not meet the bid bond forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidding entity within 90 days of the public announcement of the contract suppliers for such product category and area. As aforementioned, this requirement was implemented as part of the CY 2016 ESRD PPS final rule (81 FR 77834), so § 414.412(h) now requires that bidding entities obtain bid surety bonds, and if an entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category/CBA combination, and the entity does not accept the contract offered, the bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective bonding company. Further detailed conditions of the surety bonds were also clarified in the final rule (81 FR 77931). The bid bond requirement is mentioned here in the background section of this proposed rule because bid bond forfeiture is tied to composite bids under the DMEPOS CBP, and this rule proposes to change how composite bids are defined and to implement lead item pricing under the DMEPOS CBP.

Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. The DMEPOS CBP also includes provisions to ensure beneficiary access to quality DMEPOS items and services. Section 1847(b)(2)(A) of the Act directs the Secretary to award contracts to entities only after a finding that the entities meet applicable quality and financial standards and beneficiary access to a choice of multiple suppliers in the area is maintained, that is, more than one contract supplier is available for the product category in the area.

Sections 1847(b)(6)(A)(i) and (b)(6)(A)(ii) of the Act provide that payment will not be made under Medicare Part B for items and services furnished under the CBP unless the supplier has submitted a bid to furnish those items and has been awarded a contract. Therefore, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract. In past rounds of

competition, CMS has allowed a 60-day bidding window for suppliers to prepare and submit their bids. Our regulation at § 414.412 specifies the rules for submission of bids under the DMEPOS CBP. Each bid submission is evaluated and contracts are awarded to qualified suppliers in accordance with the requirements of section 1847(b)(2) of the Act and § 414.414, which specifies conditions for awarding contacts. Under the Round 2 and Round 1 Recompete competitions, 92 percent of suppliers accepted contract offers at the SPAs set through the competitions. In addition, CMS reviewed all contract suppliers based on financial standards when evaluating their bids. This process includes review of tax records, credit reports, and other financial data, which leads to the calculation of a score, similar to processes used by lenders when evaluating the viability of a company. All contract suppliers met the financial standards established for the program. Before awarding contracts, each bid is screened and evaluated to ensure that it is bona fide so that CMS can verify that the supplier can provide the product to the beneficiary for the bid amount, and those that fail are excluded from the competition. Approximately 94 percent of bids screened as part of the Round 2 and Round 1 Recompete competitions were determined to be bona fide.

Section 1847(b)(6)(D) of the Act requires that appropriate steps be taken to ensure that small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS CBP. We have established a number of provisions to ensure that small suppliers are given an opportunity to participate in the DMEPOS CBP. For example, under § 414.414(g)(1)(i), we have established a 30 percent target for small supplier participation; thereby ensuring efforts are made to award at least 30 percent of contracts to small suppliers. Also, CMS worked in coordination with the Small Business Administration and based on advice from the PAOC to develop an appropriate definition of ''small supplier'' for this program. Under § 414.402, a small supplier is one that generates gross revenues of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue. Under § 414.418, small suppliers may join together in ''networks'' in order to submit bids that meet the various program requirements. A majority of the bids used in establishing SPAs come from small suppliers with a history of furnishing items in the CBAs.

B. Current Method for Submitting Bids and Selecting Winners

In the DMEPOS CBP, CMS awards contracts to suppliers for furnishing multiple items and services needed in a given CBA that fall under a product category (for example, respiratory equipment). The product categories are mostly large and include multiple items used for different purposes (for example, the respiratory equipment category includes oxygen equipment and positive pressure airway devices and multiple related accessories) based on past feedback from stakeholders to promote easy access for beneficiaries and referral agents to receive all items in a product category from one location, and to prevent instances where a supplier wins a contract for one product category but loses the competitions for several other product categories. Because multiple bids for individual items are submitted when competing to become a contract supplier for the product category of items and services as a whole, it is necessary to calculate a composite bid for each bidding supplier to determine the lowest bids for the category as a whole. In accordance with § 414.402, a composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers. Using a composite bid is a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category.

In order to compute a composite bid, a weight must be applied to each item in the product category. The weight of an item is based on the beneficiary utilization or demand of the individual item compared to other items within that product category based on historic Medicare claims. Item weights are used to reflect the relative market importance of each item in the product category. Table 18 depicts the calculation of the item weights for a supplier's bid. The expected volume for items A, B, and C are 5, 3, and 2 units, respectively, for a total volume of 10 units. The item weight for item A is 0.5 (5/10), the weight for item B is 0.3 (3/10), etc. The total item weight for the supplier's bid is 1.

TABLE 18—ITEM WEIGHTS

Item	A	B	C	Total
Units	5	3	2	10
Item Weight	0.5	0.3	0.2	1

The composite bid for a supplier equals the item weight multiplied by the item bid summed across all items in the product category. For example, supplier 1 bid $1.00 for item A, $4.00 for item B and $1.00 for item C. The composite bid for Supplier 1 = (0.5 * $1.00) + (0.3 * $4.00) + (0.2 * $1.00) = 1.90. Table 19 shows the expected cost of the bundle based on each supplier's bids. The expected costs are directly proportional to the composite bids; the factor of proportionality is equal to the total number of units (10) in the product category. The composite bid is used to determine the expected costs for all of the items in the product category based upon expected volume.

TABLE 19—COMPOSITE BIDS BY SUPPLIER

Item	A	B	C	Composite bid	Product category bid (cost of bundle)
Units	5	3	2		
Item weight	0.5	0.3	0.2		
Supplier 1 bid	$1.00	$4.00	$1.00	$1.90	$19.00
Supplier 2 bid	3.00	5.00	3.00	3.60	36.00

TABLE 19—COMPOSITE BIDS BY SUPPLIER—Continued

Item	A	B	C	Composite bid	Product category bid (cost of bundle)
Supplier 3 bid	3.00	4.00	3.00	3.30	33.00
Supplier 4 bid	2.00	2.00	2.00	2.00	20.00
Supplier 5 bid	2.00	4.00	2.00	2.60	26.00
Supplier 6 bid	2.00	3.00	2.00	2.30	23.00
Supplier 7 bid	3.00	3.00	2.00	2.80	28.00
Supplier 8 bid	3.00	4.00	2.00	3.10	31.00
Supplier 9 bid	2.00	3.00	3.00	2.50	25.00
Supplier 10 bid	3.00	4.00	1.00	2.90	29.00
Supplier 11 bid	3.00	2.00	3.00	2.70	27.00

After computing composite bids for each supplier, a pivotal bid is established for each product category in each CBA. In accordance with § 414.402, pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for items in that category. As explained in the 2007 DMEPOS final rule (72 FR 18039), demand for items and services is projected using Medicare claims data for allowed services during the previous two years, trended forward to the contract period. Table 20 shows the pivotal bid is the point where expected combined capacity of the bidders is sufficient to meet expected demands of beneficiaries for items in a product category. In Table 20, the projected demand is 1,800 units, therefore the composite bid for supplier 7 represents the pivotal bid, since the cumulative capacity of 1,845 would exceed the projected demand of 1,800. As a result of the determination of the pivotal bid, suppliers 1, 4, 6, 9, 5, 11 and 7 are selected as winning suppliers for the product category in the CBA. However, suppliers 10, 8, 3, and 2 are not selected as winning suppliers for the product category in the CBA and are eliminated from the competition.

TABLE 20—DETERMINING THE PIVOTAL BID FOR PRODUCT CATEGORY POINT WHERE BENEFICIARY DEMAND (1,800) IS MET BY SUPPLIER CAPACITY

Supplier No.[1]	Composite bid	Supplier capacity	Cumulative capacity	Result
1	$1.90	250	250	Winning bid.
4	2.00	300	550	Winning bid.
6	2.30	0	550	Winning bid.
9	2.50	300	850	Winning bid.
5	2.60	360	1,210	Winning bid.
11	2.70	275	1,485	Winning bid.
7	2.80	360	1,845	Pivotal bid.
10	2.90	200	2,045	Losing bid.
8	3.10	300	2,345	Losing bid.
3	3.30	200	2,545	Losing bid.
2	3.60	25	2,570	Losing bid.

[1] By ascending composite bid.

C. Current Method for Establishing SPAs

For competitively bid items and services furnished in a CBA, the SPAs replace the Medicare allowed amounts established using the lower of the supplier's actual charge or the payment amount recognized under sections 1834(a)(2) through (7), 1834(h), and 1842(s) of the Act. We discussed various options for determining the SPA for individual items under the DMEPOS CBP during the notice and comment rulemaking conducted in 2006 and 2007 (71 FR 25653 and 72 FR 17992, respectively), including using the minimum winning bid, using the highest winning bid, using the median of winning bids, and using an average adjusted price methodology similar to the methodology used in competitive bidding demonstrations mandated by section 4319 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). A detailed discussion of the various options considered for determining the SPA for individual items under the DMEPOS CBP can be found in the 2007 DMEPOS final rule (72 FR 17992, 18044 through 18047). Through rulemaking, we finalized using the median of bids submitted for each item by winning bidders in each CBA as the methodology for establishing the SPA for each item in each CBA.

Under the current methodology for establishing SPAs at § 414.416, for individual items within each product category in each CBA, the median of the winning bids for each item is used to establish the SPA for that item in each CBA. The individual items are identified by the appropriate HCPCS codes. In cases where there is an even number of winning bids for an item, the SPA is equal to the average (mean) of the two bid prices in the middle of the array. Table 21 illustrates this method.

TABLE 21—MEDIAN OF THE WINNING BIDS METHODOLOGY

Item	A	B	C	Composite bid
Supplier 1 bid	$1.00	$4.00	$1.00	$1.90
Supplier 4 bid	2.00	2.00	2.00	2.00
Supplier 6 bid	2.00	3.00	2.00	2.30
Supplier 9 bid	2.00	3.00	3.00	2.50
Supplier 5 bid	2.00	4.00	2.00	2.60
Supplier 11 bid	3.00	2.00	3.00	2.70
Supplier 7 bid (pivotal bid)	3.00	3.00	2.00	2.80
Median/SPA	2.00	3.00	2.00	.....

We stated in 2007 that we believed that setting the SPA based on the median of the winning bids satisfies the statutory requirement that SPAs are to be based on bids submitted and accepted. We believed that this methodology results in a single payment for an item under a competitive bidding program that is representative of all acceptable bids, not just the highest or the lowest of the winning bids for that item. The median is also not influenced by outliers at the extremes of the data set. This methodology also has the advantage of being easily understood by bidding suppliers.

We received several comments on determining the SPA as a part of the rulemaking process for the 2007 DMEPOS final rule (72 FR 18046). Most of the commenters disagreed with the median bid methodology and supported the average adjusted price methodology. Numerous commenters suggested that CMS use the average adjusted price methodology that was used during the BBA demonstrations because suppliers were paid at least as much as they bid in aggregate, and commenters believed that the average adjusted price methodology would provide sufficient protections to encourage small suppliers to bid. Several commenters indicated that if contract suppliers with bids above the median amount cannot furnish items and services at payment amounts set below their bid amounts, demand for items and services might not be met and access to necessary items and services would be impaired. The commenters raised concerns that all bids would be equal in terms of establishing the median amount, and bids from small suppliers that only furnish a small percentage of the overall demand for items and services would have the same weight as bids from suppliers that would be responsible for furnishing the majority of the items and services. Other commenters suggested that the use of the median bid favors large chain suppliers that deliver a large volume of items and services.

The average adjusted price methodology for establishing the SPA for an item was discussed in the 2007 DMEPOS final rule (72 FR 18045). This methodology involved using the average of the winning bids adjusted up to the point where the adjusted bids for each supplier in the winning range equals the level of the pivotal bid. This type of methodology was used during the competitive bidding demonstrations mandated by section 4319 of the BBA. The first step of the methodology is to calculate the average of the winning bids per individual item. The second step is to calculate the average of the composite bids for the winning suppliers by taking the sum of the composite bids for all winning suppliers in the applicable CBA and dividing by the number of winning suppliers. The third step determines an adjustment factor by dividing the composite bid for the pivotal bidder by the average composite bid, and using this factor to increase every winner's overall bids for a product category to the level of the pivotal bidder's composite bid. The fourth step multiplies the average of the winning bids per item by the adjustment factor to adjust all bids up to the point of the pivotal bid, so that all winners would be paid for furnishing all items and services in the product category (the composite payment) equal to the composite bid of the pivotal bidder. This amount would become the SPA for the individual item. This is the price that all contract suppliers within a CBA would be paid for that product as illustrated in Table 22.

TABLE 22—AVERAGE ADJUSTED PRICE METHODOLOGY

Item	A	B	C	Average composite bid	Composite bid [1]
Item weight	0.5	0.3	0.2		
Supplier 1 bid	$1.00	$4.00	$1.00	.....	$1.90
Supplier 4 bid	2.00	2.00	2.00	.....	2.00
Supplier 6 bid	2.00	3.00	2.00	.....	2.30
Supplier 9 bid	2.00	3.00	3.00	.....	2.50
Supplier 5 bid	2.00	4.00	2.00	.....	2.60
Supplier 11 bid	3.00	2.00	3.00	.....	2.70
Supplier 7 bid (pivotal bid)	3.00	3.00	2.00	.....	2.80
Average of winning bids	2.14	3.00	2.14	$2.40	.....
Adjustment factor [2]	1.167	1.167	1.167	.....	.....
Average adjusted price/SPA	2.50	3.50	2.50	.....	.....

[1] Sum of item bids multiplied by item weights.

[2] The adjustment factor is equal to the pivotal bid ($2.80 in this example) divided by the average composite bid ($2.40 in this example). The SPA is established by multiplying the average of the winning bids for each item by the adjustment factor.

This methodology, similar to the one used under the BBA demonstrations from October 1, 1999 through December 31, 2002, results in payment to all winning suppliers at the pivotal bid (or highest winning composite bid) level. Under the BBA demonstrations, the adjustment factor varied by supplier and was based on the pivotal composite bid divided by the individual, winning supplier's composite bid, and the average of the prices was calculated after the bids were adjusted rather than before they were adjusted. Both versions of the average adjusted price methodology result in pricing at the pivotal bid level. For example, in Table 22 the methodology used under the BBA demonstrations would have resulted in SPAs of $2.46, $3.58, and $2.48 for items A, B, and C, respectively. However, when factoring in the expected percentage of total services made up by each item in the product category (item weight), both versions of the average adjusted price methodology result in payment at the pivotal bid level:

Table 22: (0.5 * $2.50) + (0.3 * $3.50) + (0.2 * $2.50) = $2.80

BBA demonstrations: (0.5 * $2.46) + (0.3 * $3.58) + (0.2 * $2.48) = $2.80

Using either version, the overall payment for the product category equals or exceeds the individual composite bids of $1.90, $2.00, $2.30, $2.50, $2.60, $2.70 and $2.80. We chose not to propose this approach because we believed that this approach is not reflective of all of the winning bids accepted. In addition, we stated that we were concerned that this methodology may be confusing and overly complicated (72 FR 18046).

Two additional methodologies for determining the SPA for individual items under the DMEPOS CBP include the minimum bid methodology ($1.00, $2.00, and $1.00 in the example above) and the maximum bid methodology ($3.00, $4.00, and $3.00 in the example above). More detailed explanations of these methods can be found in the 2007 DMEPOS final rule (72 FR 17992, pages 18044 through 18047). We did not support either methodology because they only reflect the bid of a single supplier and may be an outlier in the overall bid for the item. A methodology that uses a straight mean is most affected by outliers, since all values in a sample are given the same weight when calculating mean. A value that is far removed from the mean is going to likely skew results.

D. Provisions of the Proposed Rule

We believe that two proposed reforms to the DMEPOS CBP would simplify the program, eliminate the possibility for price inversions, and ensure the long term sustainability of the program.

1. Lead Item Pricing for all Product Categories Under the DMEPOS CBP

In the 2016 ESRD PPS final rule (81 FR 77945), we established alterative rules for submitting bids and determining SPAs for certain groupings of similar items with different features under the DMEPOS CBP. As discussed in the rule, price inversions result under the CBP when different item weights are assigned to similar items with different features within the product category. To prevent this from occurring under future competitions, we established an alternative ''lead item'' bidding method for submitting bids and determining single payment amounts for certain groupings of similar items (for example, walkers) with different features (wheels, folding, etc.) under the DMEPOS CBP. Under this alternative bidding method, one item in the grouping of similar items would be the lead item for the grouping for bidding purposes. The item in the grouping with the highest total national allowed services (paid units of service) during a specified base period would be considered the lead item of the grouping. CMS established a method for calculating SPAs for items within each grouping of similar items based on the SPAs for lead items within each grouping of similar items (81 FR 42878). Under § 414.416(b)(3), in the case of competitions where bids are submitted for an item that is a combination of codes for similar items within a product category as identified under § 414.412(d)(2), the single payment amount for each code within the combination of codes is equal to the single payment amount for the lead item or code with the highest total nationwide allowed services multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia (DC), Puerto Rico, and the U.S. Virgin Islands) for the code to the average of the 2015 fee schedule amounts for all areas for the lead item. Beginning in 2016, the fee schedule amounts used to pay claims in non-CBAs were adjusted based on information from the CBP. Thus, the 2015 fee schedule amounts were the last fee schedule amounts that were not adjusted based on SPAs for low weight items (for example, hospital beds without side rails) that in some cases were higher than the SPAs for other similar items in the same product category with more features (for example, hospital beds with side rails). The relative difference in the cost of the items (for example, hospital beds with side rails cost more than hospital beds without side rails) is reflected in the unadjusted fee schedule amounts in that the unadjusted fee schedule amounts for hospital beds with side rails are higher than the fee schedule amounts for hospital beds without side rails, and not in the adjusted fee schedule amounts, where the adjusted fee schedule amounts for hospital beds with side rails are not higher than the fee schedule amounts for hospital beds without side rails. For this reason, we use the unadjusted fee schedule amounts for 2015 to determine the relative difference in the cost of different items (for example, hospital beds with side rails compared to hospital beds without side rails).

Under the CBP, in all rounds since 2011, we found price inversions for groupings of similar items within the following categories: Standard power wheelchairs, walkers, hospital beds, enteral infusion pumps, TENS devices, support surface mattresses and overlays and seat lift mechanisms. We consider the price of an item inverted when a more complicated item is cheaper than a simple version. For instance, when a walker without wheels costs more than a walker with wheels. The detailed method, examples, and responses to public comments regarding lead item bidding were explained in the 2016 ESRD PPS final rule (81 FR77945 through 77949). We are now proposing to establish a similar lead item pricing methodology for all items and all product categories under the DMEPOS CBP. We propose that the methodology would now apply to all items in the product category rather than groupings of items within a product category. We also propose that the lead item would be identified based on total national allowed charges rather than total national allowed services. We believe that lead item pricing would address all price inversions we have already identified as well as potential future price inversions for other items. The lead item pricing methodology proposed in this rule is therefore similar to, but different than the lead item bidding methodology we finalized in previous rulemaking. This would not be an alternative bidding method, but would replace the current bidding method, where bids are submitted for each item in the product category, for all items. Since the bid for the lead item would be used to establish the SPAs for both the lead item and all other items in the

product category, we are referring to this proposed policy as ''lead item pricing'' rather than ''lead item bidding.'' We are proposing to implement lead item pricing and change the methodology for establishing SPAs under the CBP for a number of reasons.

We believe lead item pricing would greatly reduce the complexity of the bidding process and the burden on suppliers since they would no longer have to submit bids for numerous items in a product category. For some product categories, there are hundreds of items, and many suppliers submit bids for multiple product categories and in multiple CBAs. The more bids a supplier has to submit, the more time it takes to complete the bidding process and the greater the risk for keying errors, which have disqualified bidders in the past, reducing the level of competition and opportunity for savings under the program. Lead item pricing would also eliminate the need for item weights and calculation of composite bids based on item weights. This would greatly eliminate the burden for suppliers since they would no longer have to submit bids for each individual item in a product category.

Several issues related to this lead item pricing proposal warrant discussion. First, lead item pricing would apply to all items in each product category, including all codes for base equipment (for example, power wheelchairs) and all codes for accessories for base equipment (for example, wheelchair batteries). Bids for the lead item (for example, one of the power wheelchair codes), would therefore be used to establish the SPA for the code for the lead item, other codes for power wheelchairs other than the lead item, and codes for accessories used with the base equipment (in this example, various types of power wheelchairs). Examples of how this pricing method would work are in section V.D.2 of this proposed rule.

Second, it is likely that some of the larger, conglomerate product categories established to promote ''one stop shopping'' for beneficiaries and referral agents would need to be split into multiple product categories so that lead item pricing is not implemented for categories that include different types of base equipment. Such categories include general home equipment (hospital beds, support surfaces, commode chairs, patient lifts, and seat lifts), respiratory equipment (oxygen and oxygen equipment, continuous positive airway pressure devices, and respiratory assist devices), and standard mobility equipment (walkers, standard manual wheelchairs, standard power wheelchairs, and scooters). We believe that it would be overly complex and confusing to establish prices for one type of equipment (for example, power wheelchairs) based on bids submitted for another type of equipment (for example, walkers). We believe it would be more straightforward for suppliers to submit a lead item bid for one code for one type of base equipment (for example, group 2, captains chair power wheelchair, which is a lead item because it has the highest allowed charges) that would be used to establish payment amounts for all similar types of the base equipment that is, power wheelchairs (for example, groups 1 and 2, captains chair and sling seat versions, and equipment accommodating various patient weight capacities) and accessories used with the various power wheelchairs (for example, batteries, arm pads, and tires).

Third, as part of the proposal to move to lead item pricing, we are proposing to establish a new definition under § 414.402 for ''lead item,'' and we are proposing to revise the current definitions for ''bid'' and ''composite bid'' under § 414.402. We propose to revise the definition of ''bid'' to include the words ''or items'' after the word ''item''. The definition of ''bid'' would read as follows ''*Bid* means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.'' We are proposing this change because under lead item pricing, the bid for a lead item includes the supplier's bid for furnishing all of the items in the product category and not just the lead item.

We propose to revise the definition of ''composite bid''. The definition would read as follows ''*Composite bid* means the bid submitted by the supplier for the lead item in the product category.''

Currently, the supplier's bid amounts for multiple items in the product category are weighted and summed to generate the supplier's composite bid for that product category. Under lead item pricing, the supplier's bid amount for the lead item is the composite bid. In addition, the bids for the lead items would be used to determine the SPAs for the rest of the items in the product category. We would educate suppliers regarding how pricing for all of the items in the product category would be established based on the bids submitted for the lead item, and that they should consider their costs for furnishing the various items in the product category when submitting their bid for the lead item.

As indicated in section V.A of this proposed rule, section 1847(a)(1)(G) of the Act and our regulations require that bidding suppliers obtain bid surety bonds when participating in future competitions under the CBP. If the supplier is offered a contract for any product category for a CBA, and its composite bid for such product category and area is at or below the median composite bid rate for all bidding suppliers included in the calculation of the SPAs for the product category/CBA combination, the supplier must accept the contract offered or the supplier's bid surety bond for the applicable CBA will be forfeited. Because we are proposing a change to the definition of composite bid (the composite bid would be defined as the supplier's bid for the lead item in the product category), we note that the supplier's bid for the lead item would also be treated as the ''composite bid'' for the purpose of implementing the statutory and regulatory bid surety bond requirement. Under the lead item pricing method, suppliers would forfeit their bid surety bond for a product category in a CBA if their composite bid (their bid for the lead item) is at or below the median composite bid rate for all bidding suppliers included in the calculation of SPAs for the product category and CBA and they do not accept a contract offer for the product category and CBA. In other words, the median of the winning bids for the lead item in the product category would be calculated and used to implement the bid surety bond requirement at section 1847(a)(1)(H)(i) of the Act and § 414.412(h).

We are proposing to add the definition for ''lead item'' under § 414.402. The definition of ''lead item'' would read as follows ''*Lead item* is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition. Total nationwide Medicare allowed charges means the total sum of charges allowed for an item furnished in all states, territories, and D.C. where Medicare beneficiaries reside and can receive covered DMEPOS items and services.''

Currently under § 414.412(d)(2) the ''lead item'' in the product category is described as ''the code with the highest total nationwide allowed services for calendar year 2012,'' and ''total nationwide allowed services'' is defined in § 414.402 as meaning the total number of services allowed for an item furnished in all states, territories, and DC where Medicare beneficiaries reside and can receive covered DMEPOS items and services. We are proposing to delete

the lead item bidding provision that currently appears in § 414.412(d)(2) and replace it with the proposed lead item pricing provision. We are proposing to change these descriptions and definitions as explained by replacing this language in § 414.412(d)(2) with a new definition of lead item in § 414.402. We believe that using allowed charges rather than allowed services is a better way to identify the lead item in a product category for the purpose of implementing lead item pricing because the item with the highest allowed charges is the item that generates the most revenue for the suppliers of the items in the product category. The item with the most allowed services is not always the item that generates the most revenue for the supplier. For example, there are far more allowed services for NPWT dressings than NPWT pump rentals, but the revenue generated by the pump rentals is more than double the revenue generated by the dressings. Therefore, the item with the most allowed charges in the product category (the NPWT pump rentals) generates more revenue for the suppliers than the item with the most allowed services in the product category (the NPWT dressings). We note that in most cases the item with the most allowed charges would also be the item with the most allowed services, but in cases where this is not true, we believe that the lead item should be the one that generates the most revenue for suppliers as opposed to the one that has the higher number of allowed services.

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under the CBP unless the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. In order to implement this requirement for assurance of savings under the CBP, we propose to revise § 414.412(b)(2) to require that the supplier's bid for each lead item and product category in a CBA cannot exceed the fee schedule amount that would otherwise apply to the lead item without any adjustments based on information from the CBP.

Finally, we propose to amend the conditions for awarding contracts under the CBP in § 414.414(e) related to evaluation of bids under the CBP. Currently, this section indicates that CMS evaluates bids submitted for items within a product category, and that expected beneficiary demand in a CBA is calculated for items in the product category. We are proposing to change this section to indicate that CMS evaluates composite bids submitted for the lead item within a product category, and that expected beneficiary demand in a CBA is calculated for the lead item in the product category. We are proposing that under the lead item pricing methodology, CMS would calculate expected beneficiary demand and total supplier capacity based on the lead item in the product category when evaluating bids. Currently, beneficiary demand for items in a product category and supplier capacity for furnishing items in the product category are calculated based on historic utilization of the items making up at least 80 percent of the total expenditures for the product category as a whole. The demand for these items is trended forward to the contract period by the projected growth in beneficiary population in the CBA and utilization of the items in the product category. The pivotal bid is where total supplier capacity for furnishing the items within a product category meets projected beneficiary demand for the items. Projected demand for items within a product category and supplier capacity for meeting the projected demand for items within a product category are calculated by adding the projected demand and supplier capacity for those items in the product category that make up 80 percent of the total expenditures for the product category. It is assumed that the suppliers with the capacity to furnish the items making up 80 percent of the total expenditures for the product category would also have the capacity to furnish the remaining items in the product category as well. This has proven to be true. Under lead item pricing, we are proposing that projected demand and supplier capacity would only be calculated for the lead item for the purpose of determining or establishing the pivotal bid. In other words, the winning range of suppliers would be set based on where the cumulative capacity of suppliers for furnishing the lead item equals or exceeds the projected beneficiary demand for the lead item. It is assumed that the suppliers with the capacity to furnish the lead item in the product category would also have the capacity to furnish the remaining items in the product category as well. We believe this change would have a minimal impact on the number of contracts awarded under the program, with the exception of CPAP devices and accessories. For this category of items, the CPAP device would be the lead item, but there are also several codes for accessories (masks, tubing, etc.) where total allowed charges are close to the allowed charge total for the CPAP device itself. Establishing projected demand and supplier capacity based on the CPAP device alone could result in a drop in the number of winning suppliers; however, we believe that suppliers that have the capacity to meet projected beneficiary demand for rental of the CPAP device would also have the capacity to furnish the accessories used with the devices they are furnishing. In addition, the 20 percent cap on supplier capacity would still be in effect, which limits the capacity of suppliers, including large, national chain suppliers, to 20 percent of projected demand, even if these suppliers could meet far more than 20 percent of beneficiary demand for CPAP devices and accessories.

In summary, we propose to amend §§ 414.402, 414.412, and § 414.414 to change the definitions, the methodology for the calculation of SPAs, and the evaluation of bids under the CBP to reflect and establish the lead item pricing methodology.

2. Calculation of Single Payment Amounts (SPAs) Using Maximum Winning Bids for Lead Items

We propose to revise § 414.416 to change the methodology for calculating SPAs under the CBP. The SPA for the lead item in each product category and CBA would be based on the maximum or highest amount bid for the item by suppliers in the winning range as illustrated in Table 23. The SPAs for all other items in the product category would be based on a percentage of the maximum winning bid for the lead item. Specifically, the SPA for a non-lead item in the product category would be equal to the SPA for the lead item multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, DC, Puerto Rico, and the U.S. Virgin Islands) for the item to the average of the 2015 fee schedule amounts for all areas for the lead item. Thus, the SPAs for a non-lead item would be based on the relative difference in the fee schedule amounts for the lead and non-lead item before the fee schedule amounts were adjusted based on information from the CBP. For example, if the average 2015 fee schedule amount for a non-lead item such as a wheelchair battery is $107.25, and the average 2015 fee schedule amount for the lead item (Group 2, captains chair power wheelchair) is $578.51, the ratio for these two items would be computed by dividing $107.25 by $578.51 to get 0.18539. Multiplying $578.51 by 0.18539 then generates the amount of $107.25. Under the lead item pricing methodology, if the maximum winning bid for the lead item in this example (Group 2, captains chair power wheelchair) is used to compute an SPA

of $433.88 for this lead item, then the SPA for the non-lead item in this example (wheelchair battery) would be computed by multiplying $433.88 by 0.18539 to generate an SPA of $80.44 for the non-lead item (wheelchair battery).

We believe that establishing the SPA for the lead item based on the maximum winning bid rather than the median of winning bids could also further simplify the bidding process and better ensure the long term sustainability of the CBP. The maximum winning bid is the bid for the lead item submitted by the supplier with the pivotal bid, defined in § 414.402 as the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category. Under the proposed revised definition of composite bid, each supplier's bid for the lead item would be their composite bid. In no case would a supplier in the winning range be paid an amount for the lead item in a product category that is less than its bid amount for the lead item, or its composite bid, for the product category as a whole. We believe that this is the best way to ensure that the supplier can furnish the quantity of items and services it indicates it can furnish with its bid. As an alternative to using median bids to establish SPAs, we are proposing to use the maximum winning bid for the lead item in a product category to establish the SPAs for the rest of the items in the product category in order to ensure long term sustainability of the DMEPOS CBP. We believe that lead item pricing based on the maximum winning bid for the lead item is the best way to ensure that the supplier can furnish the quantity of items and services it indicates it can furnish with its bid because all suppliers in the winning range would be paid at least what they bid for the lead item or more. Currently, suppliers are paid based on the median of the winning bids for each item, which results in many suppliers being paid less than the amount they bid for an item, which could potentially lead to beneficiary access problems for these items if the SPA based on the median of the winning bids is not sufficient to cover the supplier's costs for furnishing the quantity of items they indicated that they could furnish with their bid. Currently under the CBP, certain suppliers can be offered contracts after the initial contract awards are made if necessary to ensure access to items and services. These suppliers are suppliers that had composite bids above the pivotal bid, so their bids are even further removed from the median bid levels than the suppliers initially awarded contracts. As median bid levels continue to decline over time, we believe that it is possible that many of the suppliers with bids above the median would not be willing or able to accept contracts for items and services with SPAs that were set using the median of winning bids. We believe this could potentially jeopardize the program. If there are not enough suppliers willing to accept contract offers and meet beneficiary demand, then this would result in no contracts or payments at SPA levels set too low to ensure access. We believe this possible scenario could be avoided by changing the way that the SPAs are calculated, and using the proposed maximum winning bid for the lead item in a product category to establish the SPAs for all items in the product category, rather than using the median of winning bids to establish the SPA for each item in a product category. Also, by applying lead item pricing to all items, it would eliminate price inversions associated with suppliers bidding high for low weight items, since items weights and bids for low weight items would no longer be used to establish SPAs for items under the CBP.

Bids from small suppliers that are only awarded contracts in order to help meet the small supplier target would not be used to determine the maximum winning bid because these contracts are awarded after the SPAs are established. Under § 414.414(g)(1)(i), we established a 30 percent target for small supplier participation in the CBP; thereby ensuring efforts are made to award at least 30 percent of contracts to small suppliers. If less than 30 percent of the suppliers in the winning range (suppliers at or below the pivotal bid) are not small suppliers, additional contracts are offered to small suppliers who bid above the pivotal bid in order to attempt to meet this 30 percent small supplier target. However, the bids above the pivotal bid have not been used to calculate the SPA in past competitions, and will not be used to calculate the SPA going forward. If small suppliers who are offered contracts do not accept them, we may not meet the small supplier target, but this refusal of the contract offers would not result in an access problem. The small supplier target is just a target for enhancing participation of small suppliers in the CBP and is not a threshold that must be met in order to meet demand for items and services. Currently, small suppliers not in the winning range who are only offered contracts in an attempt to meet this target must accept payment at the median of the winning bids for each item, which in most cases are amounts that are below what they bid for the item. While SPAs based on the proposed maximum winning bids would still be below what these suppliers bid, they are generally going to be closer to the amounts they bid than the SPAs based on the median of the winning bids.

Likewise, bids from other suppliers awarded contracts after the SPAs are established are not currently used to determine the SPAs and would not be used to determine the maximum winning bid. Currently, in very limited cases, suppliers are offered and awarded contracts after the SPAs are established and contract offers are made because of errors that were made in the bid evaluation process. Also, additional contracts can be offered at any point during the contract period if necessary to ensure beneficiary access to items and services. The SPAs are not recalculated in these situations because it would be very disruptive and logistically challenging to change the SPAs and repeat the contracting process each time an additional contract is offered and accepted. The process for completing all of the steps necessary for CMS to implement a competition under the CBP from the time the competition is announced and suppliers are registered to bid in DBids (the online bidding system) to the time the contract period begins already takes approximately 2 years.

Under the current methodology for establishing SPAs, for individual items within each product category in each CBA, the median of the winning bids for each item is used to establish the SPA for that item in each CBA, as illustrated in Table 21. The proposed methodology of using the maximum winning bids to establish SPAs is illustrated in Table 23.

TABLE 23—PROPOSED MAXIMUM WINNING BIDS METHODOLOGY

Supplier bids	Bid amounts for the lead item
Supplier 1 bid	$1.00
Supplier 4 bid	2.00
Supplier 6 bid	2.00
Supplier 9 bid	2.00
Supplier 5 bid	2.00
Supplier 11 bid	3.00
Supplier 7 bid (pivotal bid)	3.00
Maximum bid/SPA	3.00

As shown in this Table 23, the maximum winning bid, the pivotal bid, and the SPA are all equal.

We stated in the 2007 DMEPOS final rule that we believed that setting the SPA based on the maximum of the winning bids is not representative of all bids submitted. However, we now believe that using the maximum winning bid amount for the lead item to establish the SPAs and paying most contract suppliers more than they bid helps to ensure access and long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Using the maximum winning bid for the lead item to establish SPAs addresses criticism from stakeholders that the use of median bids to establish SPAs results in CMS paying approximately half of the winning suppliers below what they bid for the item. Using the maximum winning bid is also strongly supported by the supplier community, as expressed in comments described in the preamble to the 2007 DMEPOS final rule (72 FR 18046). Under the CBP, suppliers have consistently accepted contract offers 92 percent of the time, even though the median bid levels have trended lower with each successive round of competitions. However, if bid levels continue to trend downward, we believe this could ultimately result in many suppliers rejecting contract offers, to the point where there may not be enough suppliers accepting contracts to meet demand for items and services. Table 24 shows the average SPAs for seven high volume items that have been included in all rounds of bidding and how they have changed with each successive recompete of the contracts.

TABLE 24—CHANGE IN AVERAGE SPAS OVER ROUNDS OF BIDDING

Round	Year	SPA	Year	SPA	Change %
E1390—Oxygen Concentrator/Oxygen and Oxygen Equipment					
1	2011	$116.16	2014	$95.74	−18
1	2014	95.74	2017	77.97	−19
2	2013	93.07	2016	76.84	−17
E0601—CPAP					
1	2011	$582.31	2014	$518.58	−11
1	2014	518.58	2017	426.76	−18
2	2013	466.02	2016	397.60	−15
K0823—Group 2 Standard Power Wheelchair					
1	2011	$2,554.22	2014	$2,189.28	−14
1	2014	2,189.28	2017	1,770.17	−19
2	2013	1,889.48	2016	1,785.41	−6
B4035—Daily Supplies for Enteral Nutrition by Pump					
1	2011	$7.50	2014	$5.79	−23
1	2014	5.79	2017	5.22	−10
2	2013	5.98	2016	5.25	−12
E0143—Folding Wheeled Walker					
1	2011	$66.13	2014	$58.79	−11
1	2014	58.79	2017	47.89	−19
2	2013	53.22	2016	45.93	−14
E0260—Semi-Electric Hospital Bed					
1	2011	$803.45	2014	$738.59	−8
1	2014	738.59	2017	615.22	−17
2	2013	703.14	2016	591.30	−16
E0277—Powered Mattress Support Surface					
1	2011	$3,197.50	2014	$2,855.09	−11
1	2014	2,855.09	2017	2,257.05	−21
2	2013	2,351.77	2016	1,748.70	−26

If the median bids continue on this downward trend, suppliers with bids above the median bid may not be able to continue to furnish items and services at the SPAs established based on the median of winning bids, and this could cause problems with securing enough contract suppliers to meet demand and could cause non-viable programs in certain areas for certain product categories. We believe establishing SPAs based on the maximum winning bid for the lead item would help prevent such a scenario from unfolding and would enhance the long term sustainability of the DMEPOS CBP. We believe current tools used to address potential access or demand issues in CBAs, such as awarding additional contracts, may become insufficient if suppliers in the upper half of the winning range (those that bid at or below the pivotal bid, but above the median) stop accepting contract offers because the SPAs over time have decreased to the point where they are unacceptable to these suppliers.

We believe that the maximum winning bid methodology would enable long term sustainability of the CBP but has some risks. This methodology could skew the data set of bids if there is an outlier. For example, in Table 23, if one

supplier bids $20 and the majority of suppliers bid between $1 and $3, this would cause the entire item price to be inaccurately skewed in one direction and would increase the cost of the item significantly. Although there are some hindrances in replacing the median bid amount methodology with the maximum winning bid methodology for determining the SPA, such as the risk of skewed bids and the risk of paying suppliers more than necessary to meet beneficiary demand, we believe that the pros of reducing burden and enhancing access to items and services and sustainability of the competitive bidding program outweigh these cons. We solicit comments on ways to minimize these risks.

With regard to the fiscal impact of the proposal to use lead item pricing and maximum winning bids to establish SPAs, we believe that use of maximum winning bids to establish SPAs for lead items would increase payment amounts and expenditures for these lead items, but would also decrease payment amounts and expenditures for many of the non-lead items, which should offset the cost of the payments for the lead items. For example, the monthly rental SPA for the NPWT pump (E2402) for the Virginia Beach, Virginia CBA is $654.89 (60 percent less than the fee schedule amount of $1,642.09) and the purchase SPA for the NPWT dressing (A6550) is $25.39 (only 3 percent less than the fee schedule amount of $26.25). In 2017, approximately $356,257 was spent on the pump in this CBA while approximately $154,752 was spent on the dressings. Under lead item pricing, code E2402 would be the lead item, and the maximum winning bid for this item under the Round 2 Recompete (2016) was $839.00 per month (49 percent less than the fee schedule amount of $1,642.09). Had this amount been paid in 2017 in the Virginia Beach CBA, it would have increased expenditures for NPWT pump (E2402) by approximately $100,159 from $356,257 to approximately $456,416. However, using lead item pricing, the price for the dressing would have decreased from $25.39 to $13.41 (49 percent less than the fee schedule amount of $26.25), which would have decreased expenditures for code A6550 by approximately $73,018 from $154,752 to approximately $81,734. The net increase in expenditures in this example would have been approximately $27,141 ($100,159 − $73,018).

In summary, we propose to amend the SPA determination methodology in § 414.416 to change the methodology from one that uses the median of winning bids for each item to establish the SPAs for each item to one that uses the maximum winning bid for the lead item to set the SPA for the lead item and the rest of the items within the product category (''non-lead items''). The SPAs for each non-lead item would be based on the relative difference in the fee schedule amounts for the non-lead item and the lead item in 2015, before the fee schedule amounts were adjusted based on information from the CBP.

Finally, we are interested in obtaining feedback from the public on whether or not certain large CBAs should be split into smaller size CBAs to create more manageable service areas for suppliers, as has been done for the New York, Los Angeles, and Chicago CBAs. We are soliciting feedback that we can consider in potentially adjusting the size and boundaries of CBAs for future competitions. There are currently nine CBAs with more than 7,000 square miles, and three of these CBAs are areas with more than 9,000 square miles. The largest CBA is the Phoenix-Mesa-Scottsdale, Arizona CBA with approximately 12,000 square miles. This CBA is comprised of the two counties, Maricopa (approximately 8,000 square miles) in the northwest and Pinal (approximately 4,000 square miles) in the southeast. One option for reducing the size of this CBA would be to split the CBA in two based on the county borders and then remove some of the large low population density zip code areas from the southwestern portion of the new Maricopa County CBA to reduce the size of this CBA. Interstate highway 10 runs west to east and then south through the northern part of the current CBA (primarily Maricopa County), while interstate highway 8 runs west to east through the southern part of the current CBA (primarily Pinal County).

The second largest CBA is the Boise City, Idaho CBA, comprised of five counties, approximately 11,800 square miles. Three zip code areas (83604, 83624, and 83650) south of the Snake River and interstate highway 84 in Owyhee County make up almost 65 percent of the area for the CBA (approximately 7,700 square miles), but only 2 percent of the population. Removing these three zip codes from the CBA would reduce the size of the CBA to a little over 4,000 square miles. The average size of the 130 CBAs is approximately 2,900 square miles. The third largest CBA is the Dallas-Fort Worth-Arlington, Texas CBA with approximately 9,100 square miles. The Dallas-Fort Worth-Arlington, Texas MSA and is made up of the two metropolitan divisions of Dallas-Plano-Irving (approximately 5,000 square miles over eight counties) and Fort Worth-Arlington (approximately 4,000 square miles over seven counties). This CBA could potentially be divided into two new CBAs based on the metropolitan divisions. The other six CBAs with more than 7,000 square miles are Riverside-San Bernardino-Ontario, California (approximately 8,900 square miles), Houston-The Woodlands-Sugar Land, Texas (approximately 8,800 square miles), Bakersfield, California (approximately 8,100 square miles), Salt Lake City, Utah (approximately 7,500 square miles), San Antonio-New Braunfels, Texas (approximately 7,300 square miles), and Atlanta-Sandy Springs-Roswell, Georgia (approximately 7,300 square miles).

We are soliciting feedback on whether certain large CBAs should be subdivided to make the areas more manageable to serve. One result of subdividing the CBAs and creating more CBAs is that suppliers who wish to bid for furnishing items and services in all of the areas that formerly would have been one area would have to incur the cost and effort of obtaining multiple bid surety bonds for the new areas rather than one bid surety bond.

VI. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

A. Background

Section 16008 of the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255) was enacted on December 13, 2016, and amended section 1834(a)(1)(G) of the Act to require in the case of items and services furnished in non-CBAs on or after January 1, 2019, that in making any adjustments to the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and (iii), 1834(a)(1)(H)(ii), or 1842(s)(3)(B) of the Act, the Secretary shall: (1) Solicit and take into account stakeholder input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.

1. Stakeholder Input Gathered in Accordance With Section 16008 of the Cures Act

Section 16008 of the Cures Act mandates that we solicit and take into

account stakeholder input in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. In order to solicit stakeholder input, we announced that we would be hosting a Medicare Learning Network (MLN) Connects™ National Provider Call (MLN Connects Call), which are educational conference calls conducted for the Medicare provider and supplier community that educate and inform participants about new policies and/or changes to the Medicare program. We announced this call through multiple CMS listservs throughout March 2017, in order to get the word out as quickly and directly as possible to our stakeholders. On March 23, 2017, CMS hosted a national provider call to solicit stakeholder input regarding adjustments to fee schedule amounts using information from the DMEPOS CBP. The national provider call was announced on March 3, 2017, and we requested written comments by April 6, 2017.

We received 125 written comments from stakeholders. More than 330 participants called into our national provider call, with 23 participants providing oral comments during the call. In general, the commenters were mostly suppliers, but also included manufacturers, trade organizations, and healthcare providers such as physical and occupational therapists. These stakeholders expressed concerns that the level of the adjusted payment amounts constrains suppliers from furnishing items and services to rural areas. Stakeholders requested an increase to the adjusted payment amounts for these areas. The written comments generally echoed the oral comments from the call held on March 23, 2017, whereby stakeholders claimed that the adjusted fees are not sufficient to cover the costs of furnishing items and services in non-CBAs and that this is having an impact on access to items and services in these areas.

The oral and written comments are organized into the following categories:

Inadequacy of Adjusted Fee Schedule Amounts: Commenters claim the adjusted fee schedule amounts do not cover the cost of furnishing the items and are not sustainable. Many commenters opposed the current adjusted payment amounts as insufficient to sustain the current cost of doing business. Some commenters stated that current reimbursement levels are below the cost of doing business. Many commenters stated they were billing non-assigned for items, or were considering billing non-assigned in the future.

Travel Distance: Commenters claim the average travel distance and cost for suppliers serving rural areas are greater than the average travel distance and cost for suppliers serving CBAs. Many commenters described farther travel distances in rural areas than in non-rural areas. (For the purpose of implementing the fee schedule adjustment methodologies at § 414.210(g), the term ''rural area'' is defined at § 414.202 and essentially includes any areas outside an MSA or excluded from a CBA).

Volume of Services: Many commenters asserted that the average volume of services furnished by suppliers, when serving non-CBAs, are lower than the average volume of services furnished by suppliers, when serving CBAs. Many commenters stated that they do not get the same increase in volume that suppliers who obtain competitive bidding contracts get, which does not allow them to have economies of scale and obtain products at lower costs.

Beneficiary Access: Many commenters stated that the adjusted fees have reduced the number of suppliers in the area, and that this has caused or will cause beneficiary access issues. Some commenters claimed that they were the only supplier in the area.

Adverse Beneficiary Health Outcomes: Commenters stated that beneficiaries are going without items and this is causing adverse health outcomes. Commenters stated that hospital readmissions and lengths of stay, falls, and fractures are increasing as a result of the fee schedule reductions.

Delivery Expenses: A few commenters provided an estimate of how much their delivery expenses cost, their estimated service radius, and the average distance traveled. Several commenters stated that they have reduced the size of their service area due to the level of reimbursement that they are receiving.

Costs in Rural Areas: Many commenters stated rural areas have unique costs, costs that are higher than non-rural areas. Similar to comments received on our CY 2015 ESRD PPS proposed rule (79 FR 40275 through 40315) and discussed in the CY 2015 ESRD PPS final rule (79 FR 66223 through 66265), some commenters stated that a 10 percent payment increase in rural areas is not enough to cover costs in rural areas. One commenter stated that non-contiguous areas, such as Alaska and Hawaii, face unique and greater costs due to higher shipping costs, a smaller amount of suppliers, and more logistical challenges related to delivery. Some commenters stated specific costs, as well as data sources, that CMS should take into account when adjusting fees in non-CBAs. These included the following: Geographic wage index factors, gas, taxes, employee wages and benefits, wear and tear of vehicle, average per capita income, training, delivery, set up, historical Medicare home placement volume, proximity to nearby CBAs, employing a respiratory therapist, electricity charges, freight charges, 24/7 service, documentation requirements, average per patient cost, licensing accreditation, surety bonds, audits, population density, miles and time between points of service, regulatory costs, vehicle insurance, and liability insurance.

Two commenters pointed to the Ambulance Fee Schedule and one commenter pointed to the Bureau of Labor Statistic Consumer Expenditure Survey as evidence that health care costs in rural areas are higher than in urban areas. Another commenter mentioned the Internal Revenue Service Mileage Rate, the minimum wage, AAA Gallon of Gasoline prices, and the price of a loaf of white bread, to highlight how the prices of such items have increased over the years, while reimbursement for DME has not.

Using the Highest Winning Bids for the Adjusted Fee Schedule Methodology: Five commenters suggested that the adjusted fee schedule amounts be based on maximum winning bids in CBAs rather than the median of winning bids in CBAs. One commenter suggested that the maximum winning bids should be the starting point for the adjustments and that additional payment should be added on to these amounts to pay for the higher costs of furnishing items and services in non-CBAs.

2. Highest Winning Bids in CBAs Analysis

Section 16008 of the Cures Act mandates that we take into account the highest amount bid by a winning supplier in a CBA in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We considered the highest amounts bid by a winning supplier for a specific item (maximum bid) in the various CBAs in Round 1 2017 and Round 2 Recompete to see if maximum bids varied in different types of areas (that is, low volume versus high volume areas, large versus small delivery service areas, areas with few suppliers versus many suppliers). We analyzed maximum bids for the lead items in each product category (those with the

highest allowed charges) and for other lower volume items. For lower volume items with low item weights, suppliers had less of an incentive to bid low on these items and therefore the maximum bids for many of these items are not significantly below the unadjusted fee schedule amounts.

For the lead items, we focused primarily on items that clearly are delivered locally such as large bulky hospital beds and oxygen equipment (concentrators and tanks) since variations in maximum bid amounts from CBA to CBA due to differences in travel distances and costs would be most noticeable for these items. There are 130 CBAs in total in Round 1 2017 and Round 2 Recompete varying greatly in size, volume, and number of suppliers. What we found is that there is no pattern indicating that maximum bids are higher for larger areas with lower volume than they are for smaller areas with higher volume.

Table 25 lists the 130 maximum bids for code E0260 (semi-electric hospital bed). We ranked the CBAs/bids from the largest maximum bid for E0260 to the lowest maximum bid for E0260. The average volume per supplier for each item is also included and ranked from 1 (lowest average volume per supplier) to 130 (highest average volume per supplier). We looked to see if lower average volumes (for example, rankings 1, 2, 3, etc.) corresponded with higher maximum bid amounts. We also looked to see if larger areas (for example, rankings 1, 2, 3, etc.) corresponded with higher maximum bid amounts.

TABLE 25—MAXIMUM BID AMOUNTS IN ROUND 1 2017 AND ROUND 2 RECOMPETE FOR CODE E0260

[Semi-Electric Hospital Bed]

Area name	Size in square miles	Size rank	Maximum winning bid E0260	Max E0260 bid rank	Average E0260 services per supplier [1]	Volume rank (low to high) E0260
Salt Lake City UT	7,473	7	$1,343.79	1	37	23
Ocala FL	1,585	88	1,325.00	2	33	17
Albuquerque NM	6,287	10	1,303.00	3	35	19
Charlotte-Concord-Gastonia NC	3,788	37	1,276.61	4	75	68
Kansas City MO	4,572	25	1,207.50	5	51	36
Seattle-Tacoma-Bellevue WA	5,872	14	1,199.00	6	34	18
Wichita KS	4,149	29	1,100.00	7	61	53
Knoxville TN	3,501	39	1,100.00	7	49	33
Honolulu HI	601	124	1,075.00	9	46	30
Portland-Hillsboro-Beaverton OR	4,399	26	1,000.00	10	61	52
McAllen-Edinburg-Mission TX	1,571	90	950.00	11	127	107
Colorado Springs CO	2,684	52	941.00	12	22	3
Nashville-Davidson-Murfreesboro-Franklin TN	6,036	12	940.00	13	68	60
Phoenix-Mesa-Scottsdale AZ	12,036	1	924.82	14	79	73
Riverside-San Bernardino-Ontario CA	8,900	4	920.00	15	53	37
Bridgeport-Stamford-Norwalk CT	625	122	897.23	16	84	77
Orlando-Kissimmee-Sanford FL	3,478	40	873.47	17	67	57
Tampa-St. Petersburg-Clearwater FL	2,513	55	850.00	18	85	78
Boise City ID	11,766	2	850.00	18	31	14
Hartford-West Hartford-East Hartford CT	1,515	94	843.92	20	138	110
Los Angeles County CA	2,232	65	840.60	21	109	96
New Haven-Milford CT	605	123	829.62	22	157	117
Boston-Cambridge-Quincy MA	2,424	59	828.19	23	166	119
Kansas City-Overland Park-Ottawa KS	2,829	48	819.00	24	36	20
Denver-Aurora-Lakewood CO	3,906	34	818.11	25	24	6
Chicago-Naperville-Arlington Heights IL	1,273	103	818.10	26	328	130
Wilmington DE	426	127	817.41	27	156	116
Fresno CA	5,958	13	816.78	28	30	12
Worcester MA	1,511	95	814.00	29	57	46
Jeffersonville-New Albany IN	1,709	82	811.56	30	95	87
Scranton-Wilkes-Barre-Hazleton PA	1,747	81	807.35	31	142	112
Greensboro-High Point NC	1,994	73	805.31	32	73	65
Indianapolis-Carmel-Anderson IN	3,994	33	800.00	33	120	101
Minneapolis-St. Paul-Bloomington MN	4,731	23	800.00	33	94	86
El Paso TX	1,013	112	800.00	33	74	66
Austin-Round Rock TX	4,220	27	800.00	33	58	47
Beaumont-Port Arthur TX	3,034	46	800.00	33	37	24
Lakeland-Winter Haven FL	1,798	80	798.88	38	71	63
Deltona-Daytona Beach-Ormond Beach FL	1,586	87	798.88	38	45	29
Silver Spring-Rockville-Bethesda MD	1,152	105	789.00	40	104	93
Augusta-Richmond County GA	1,909	76	787.00	41	101	90
Atlanta-Sandy Springs-Roswell GA	7,275	9	787.00	41	92	84
Columbia SC	3,250	43	787.00	41	74	67
Greenville-Anderson-Mauldin SC	2,711	51	787.00	41	69	61
Memphis TN	1,926	74	785.00	45	119	100
Omaha NE	2,265	63	780.65	46	28	8
Council Bluffs IA	2,085	70	780.65	46	14	1
Chester Lancaster-York Counties SC	1,810	79	780.00	48	30	10
Oklahoma City OK	5,512	15	778.68	49	59	49
Birmingham-Hoover AL	5,280	17	776.79	50	86	79

TABLE 25—MAXIMUM BID AMOUNTS IN ROUND 1 2017 AND ROUND 2 RECOMPETE FOR CODE E0260—Continued

[Semi-Electric Hospital Bed]

Area name	Size in square miles	Size rank	Maximum winning bid E0260	Max E0260 bid rank	Average E0260 services per supplier [1]	Volume rank (low to high) E0260
Chattanooga TN	1,306	99	776.27	51	45	27
Washington DC	61	130	765.00	52	110	97
Miami-Fort Lauderdale-West Palm Beach FL	5,077	20	760.20	53	159	118
Jacksonville FL	3,201	45	752.90	54	115	99
Jackson MS	4,649	24	752.90	55	82	74
Baton Rouge LA	4,027	32	752.90	55	61	51
South Haven-Olive Branch MS	2,448	57	752.90	55	55	40
Cape Coral-Fort Myers FL	785	118	752.90	55	37	22
East St. Louis IL	3,845	36	750.00	59	59	48
Catoosa Dade-Walker Counties GA	783	119	750.00	59	24	5
Pittsburgh PA	5,282	16	749.00	61	121	103
Raleigh NC	2,118	68	748.00	62	70	62
Charleston-North Charleston SC	2,588	54	748.00	62	60	50
Aiken-Edgefield Counties SC	1,571	90	748.00	62	56	43
Syracuse NY	2,385	61	742.50	65	50	34
St. Louis MO	5,267	18	739.22	66	57	45
Nassau Kings Queens-Richmond Counties NY	522	126	739.09	67	253	126
Palm Bay-Melbourne-Titusville FL	1,016	111	739.09	67	67	56
Rockingham-Strafford Counties NH	1,064	107	738.98	67	53	38
Milwaukee-Waukesha-West Allis WI	1,455	96	733.74	70	84	76
Las Vegas-Henderson-Paradise NV	1,578	89	733.01	71	47	31
Providence RI	1,034	109	728.84	72	63	55
Huntington WV	1,570	92	728.75	73	54	39
Dearborn Franklin Ohio-Union Counties IN	937	113	728.70	74	31	15
Mercer County PA	673	120	725.00	75	33	16
Aurora-Elgin-Joliet IL	2,727	50	720.00	76	120	102
Gary IN	1,878	77	719.99	77	124	105
Houston-The Woodlands-Sugar Land TX	8,827	5	714.06	78	129	108
Tulsa OK	6,269	11	710.00	79	76	70
Visalia-Porterville CA	3,377	41	705.49	80	113	98
San Francisco-Oakland-Hayward CA	2,471	56	705.49	80	92	85
San Jose-Sunnyvale-Santa Clara CA	2,679	53	705.49	80	30	13
San Diego-Carlsbad CA	4,207	28	705.49	80	30	11
Cleveland-Elyria OH	1,997	72	705.00	84	180	122
New Orleans-Metairie LA	2,422	60	705.00	84	126	106
Pierce-St. Croix Counties WI	1,296	101	703.14	86	19	2
Louisville-Jefferson County KY	2,440	58	700.00	87	139	111
Dayton OH	1,706	83	700.00	87	103	92
Cincinnati OH	2,216	66	700.00	87	101	89
Albany-Schenectady-Troy NY	2,812	49	700.00	87	95	88
Columbus OH	4,797	22	700.00	87	87	80
Youngstown-Warren-Boardman OH	1,030	110	700.00	87	63	54
Dallas-Fort Worth-Arlington TX	9,091	3	697.17	93	142	113
Baltimore-Columbia-Towson MD	2,948	47	695.52	94	190	123
Asheville NC	2,033	71	691.83	95	51	35
Bakersfield CA	8,132	6	690.00	96	24	7
Calvert Charles-Prince Georges Counties MD	1,154	104	688.85	97	101	91
Suffolk County NY	912	114	687.05	98	168	120
Port Chester-White Plains-Yonkers NY	834	116	687.05	98	129	109
Akron OH	900	115	683.00	100	90	83
Philadelphia PA	2,156	67	682.71	101	308	129
Buffalo-Cheektowaga-Niagara Falls NY	1,565	93	680.00	102	90	82
Rochester NY	3,266	42	680.00	102	77	72
Jersey City-Newark NJ	1,926	74	675.00	104	258	128
Elizabeth-Lakewood-New Brunswick NJ	2,239	64	675.00	104	258	127
Detroit-Warren-Dearborn MI	3,888	35	675.00	104	216	125
Flint MI	637	121	675.00	104	83	75
Grand Rapids-Wyoming MI	4,053	31	675.00	104	76	69
Arlington-Alexandria-Reston VA	3,226	44	675.00	104	72	64
Richmond VA	4,897	21	675.00	104	49	32
Sacramento-Roseville-Arden-Arcade CA	5,094	19	674.00	111	151	115
Orange County CA	791	117	674.00	111	68	59
Oxnard-Thousand Oaks-Ventura CA	1,290	102	674.00	111	56	44
Stockton-Lodi CA	1,391	98	674.00	111	37	21

TABLE 25—MAXIMUM BID AMOUNTS IN ROUND 1 2017 AND ROUND 2 RECOMPETE FOR CODE E0260—Continued

[Semi-Electric Hospital Bed]

Area name	Size in square miles	Size rank	Maximum winning bid E0260	Max E0260 bid rank	Average E0260 services per supplier [1]	Volume rank (low to high) E0260
San Antonio-New Braunfels TX	7,313	8	671.50	115	29	9
Camden NJ	1,674	84	670.00	116	209	124
Bronx-Manhattan NY	65	129	670.00	116	150	114
Virginia Beach-Norfolk-Newport News VA	2,089	69	670.00	116	77	71
North Port-Sarasota-Bradenton FL	1,299	100	667.98	119	45	28
Toledo OH	1,618	85	664.58	120	55	41
Covington-Florence-Newport KY	1,400	97	658.46	121	55	42
Lake-McHenry Counties IL	1,047	108	629.90	122	107	95
Allentown-Bethlehem-Easton PA	1,096	106	625.00	123	172	121
Poughkeepsie-Newburgh-Middletown NY	1,607	86	625.00	123	67	58
Kenosha County WI	272	128	618.78	125	23	4
Bristol County MA	553	125	600.00	126	105	94
Springfield MA	1,844	78	574.29	127	121	104
Little Rock-North Little Rock-Conway AR	4,085	30	574.29	127	90	81
Tucson AZ	3,675	38	574.29	127	42	26
Vancouver WA	2,285	62	574.29	127	40	25

[1] 2016 allowed services.

We found no correlation between the size of the areas and/or average volume per supplier and maximum bid amounts for code E0260. The lowest volume CBA (Council Bluffs, Iowa) had the 46th highest maximum bid for E0260 and the second lowest volume CBA (Pierce-St. Croix Counties Wisconsin) had the 86th highest maximum bid for E0260. The highest maximum bid for E0260 was from the 7,437 square mile area for Salt Lake City, Utah (the 7th largest area), but the second highest maximum bid for E0260 was from the 1,585 square mile area for Ocala, Florida (the 88th largest area).

We also analyzed the maximum bids for E0260 for states with at least 7 CBAs to see if there was any correlation between maximum bid amounts and area size, average volume per supplier, or number of suppliers and did not see any correlation between the maximum bids and these factors. California has 12 CBAs ranging in size from 791 to 8,900 square miles. Bakersfield, one of the CBAs, has the second largest service area (8,132 square miles) and lowest average volume per supplier for E0260 in 2016 (24) in California, but the maximum winning bid for E0260 for Bakersfield was lower than the maximum winning bids for seven of the eleven other CBAs, all having smaller service areas as well, with the exception of Riverside (8,900 square miles). See Table 26.

TABLE 26—ROUND 1 2017 AND ROUND 2 RECOMPETE CALIFORNIA CBA COMPARISON AND MAXIMUM BIDS FOR E0260

Area	Service area (square miles)	Population	Allowed services in 2016 (E0260)	Number of suppliers in 2016 (E0260)	Average allowed services per supplier	Maximum bid (E0260)
Bakersfield	8,132	839,631	462	19	24	$690.00
Fresno	5,958	930,450	571	19	30	816.78
San Diego	4,207	3,095,313	1,360	46	30	705.49
San Jose	2,679	1,836,911	913	30	30	705.49
Stockton-Lodi	1,391	685,306	586	16	37	674.00
Riverside	8,900	4,224,851	2,838	54	53	920.00
Oxnard	1,290	823,318	1,124	20	56	674.00
Orange County	791	3,010,232	2,596	38	68	674.00
San Francisco	2,471	4,335,391	5,729	62	92	705.49
Los Angeles County	2,232	9,818,605	11,509	106	109	840.60
Visalia-Porterville	3,377	442,179	907	8	113	705.49
Sacramento	5,094	2,149,127	5,434	36	151	674.00

Florida has 10 CBAs ranging in size from 785 to 5,077 square miles. Ocala, one of the CBAs, has the lowest volume per supplier and the highest maximum bid in Florida. However, North Point and Deltona have much lower maximum bids for E0260 but only slightly higher volume and number of suppliers and are the same size as the Ocala CBA. See Table 27.

TABLE 27—ROUND 1 2017 AND ROUND 2 RECOMPETE FLORIDA CBA COMPARISON AND MAXIMUM BIDS FOR E0260

Area	Service area (square miles)	Population	Allowed services in 2016 (E0260)	Number of suppliers in 2016 (E0260)	Average allowed services per supplier	Maximum bid (E0260)
Ocala	1,585	331,303	1,195	36	33	$1,325.00
Cape Coral-Fort Myers	785	618,754	1,189	32	37	752.90
North Port-Sarasota	1,299	702,281	2,177	48	45	667.98
Deltona	1,586	590,289	2,223	49	45	798.88
Orlando	3,478	2,134,406	6,593	98	67	873.47
Palm Bay-Melbourne	1,016	543,376	2,416	36	67	739.09
Lakeland	1,798	602,095	2,636	37	71	798.88
Tampa-St. Petersburg	2,513	2,783,243	8,059	95	85	850.00
Jacksonville	3,201	1,345,596	5,163	45	115	752.90
Miami	5,077	5,564,657	20,183	127	159	760.20

New York has 9 CBAs ranging in size from 65 to 3,266 square miles. Syracuse, one of the CBAs, has the lowest volume and highest maximum bid in New York for E0260. By contrast, the Nassau CBA has a much higher volume for E0260 and a smaller service area than the Syracuse CBA, but a maximum bid for E0260 that is very close to the maximum bid for E0260 for the Syracuse CBA. See Table 28.

TABLE 28—ROUND 2 RECOMPETE NEW YORK CBA COMPARISON AND MAXIMUM BIDS FOR E0260

Area	Service area (square miles)	Population	Allowed services in 2016 (E0260)	Number of suppliers in 2016 (E0260)	Average allowed services per supplier	Maximum bid (E0260)
Syracuse	2,385	662,577	1,599	32	50	$742.50
Poughkeepsie	1,607	670,301	2,291	34	67	625.00
Rochester	3,266	1,079,671	2,382	31	77	680.00
Buffalo	1,565	1,135,509	1,983	22	90	680.00
Albany	2,812	870,716	2,854	30	95	700.00
Port Chester	834	1,360,510	6,591	51	129	687.05
Bronx-Manhattan	65	2,970,981	9,884	66	150	670.00
Suffolk County	912	1,493,350	6,231	37	168	687.05
Nassau Kings Queens	522	6,543,684	25,839	102	253	739.09

Ohio has 7 CBAs ranging in size from 900 to 4,797 square miles. Four of the CBAs have the same maximum bid for E0260 ($700), yet the areas are not similar in size, volume, or number of suppliers. See Table 29.

TABLE 29—ROUND 1 2017 AND ROUND 2 RECOMPETE OHIO CBA COMPARISON AND MAXIMUM BIDS FOR E0260

Area	Service area (square miles)	Population	Allowed services in 2016 (E0260)	Number of suppliers in 2016 (E0260)	Average allowed services per supplier	Maximum bid (E0260)
Toledo	1,618	651,429	1,649	30	55	$664.58
Youngstown	1,030	449,130	1,199	19	63	700.00
Columbus	4,797	1,901,974	5,409	62	87	700.00
Akron	900	703,200	2,350	26	90	683.00
Cincinnati	2,216	1,625,406	4,530	45	101	700.00
Dayton	1,706	841,502	3,705	36	103	700.00
Cleveland	1,997	2,077,245	10,623	59	180	705.00

Finally, Texas has 7 CBAs ranging in size from 1,013 to 9,091 square miles. The San Antonio CBA has the lowest volume for E0260 and is a large area, but has the lowest maximum bid amount for E0260 in Texas. The McAllen CBA has the highest maximum bid amount for E0260, but is much smaller and has a much higher average volume per supplier for E0260 than the San Antonio CBA. See Table 30.

TABLE 30—ROUND 1 2017 AND ROUND 2 RECOMPETE TEXAS CBA COMPARISON AND MAXIMUM BIDS FOR E0260

Area	Service area (square miles)	Population	Allowed services in 2016 (E0260)	Number of suppliers in 2016 (E0260)	Average allowed services per supplier	Maximum bid (E0260)
San Antonio	7,313	2,142,508	1,026	35	29	$671.50

TABLE 30—ROUND 1 2017 AND ROUND 2 RECOMPETE TEXAS CBA COMPARISON AND MAXIMUM BIDS FOR E0260—Continued

Area	Service area (square miles)	Population	Allowed services in 2016 (E0260)	Number of suppliers in 2016 (E0260)	Average allowed services per supplier	Maximum bid (E0260)
Beaumont-Port Arthur	3,034	403,190	894	24	37	800.00
Austin	4,220	1,716,289	2,599	45	58	800.00
El Paso	1,013	800,647	1,110	15	74	800.00
McAllen	1,571	774,773	2,279	18	127	950.00
Houston	8,827	5,946,800	11,353	88	129	714.06
Dallas	9,091	6,417,724	14,362	101	142	697.17

We did not find any correlation between maximum winning bid amounts for code E0260 and the size of a service area or between maximum winning bid amounts for code E0260 and the volume of items and services furnished by suppliers in various areas.

Table 31 lists the 130 maximum bids in Round 1 2017 and Round 2 Recompete for code E1390 (oxygen concentrators and portable oxygen contents or tanks).

TABLE 31—MAXIMUM BID AMOUNTS FOR HCPCS CODE E1390

[Oxygen concentrator and portable contents/tanks]

Area name	Size in square miles	Size rank	Maximum winning bid E1390	Max E1390 bid rank	Average E1390 services per supplier [1]	Volume rank (low to high) E1390
Cape Coral-Fort Myers, FL	785	118	$135.50	1	108	7
Seattle-Tacoma-Bellevue, WA	5,872	14	134.17	2	222	79
Birmingham-Hoover, AL	5,280	17	132.52	3	174	49
Hartford-West Hartford-East Hartford, CT	1,515	94	130.28	4	287	108
Albuquerque, NM	6,287	10	123.00	5	224	81
Jeffersonville-New Albany, IN	1,709	82	117.60	6	278	102
Gary, IN	1,878	77	117.60	6	279	103
Indianapolis-Carmel-Anderson, IN	3,994	33	115.00	8	357	122
North Port-Sarasota-Bradenton, FL	1,299	100	110.50	9	136	19
Nashville-Davidson-Murfreesboro-Franklin, TN	6,036	12	109.00	10	185	57
Miami-Fort Lauderdale-West Palm Beach, FL	5,077	20	109.00	10	199	65
Salt Lake City, UT	7,473	7	106.00	12	375	126
Ocala, FL	1,585	88	106.00	12	108	7
Charlotte-Concord-Gastonia, NC	3,788	37	106.00	12	243	89
Kansas City, MO	4,572	25	106.00	12	315	115
Wichita, KS	4,149	29	106.00	12	412	130
Knoxville, TN	3,501	39	106.00	12	217	76
Portland-Hillsboro-Beaverton, OR	4,399	26	106.00	12	132	16
McAllen-Edinburg-Mission, TX	1,571	90	106.00	12	80	2
Colorado Springs, CO	2,684	52	106.00	12	368	124
Phoenix-Mesa-Scottsdale, AZ	12,036	1	106.00	12	168	44
Riverside-San Bernardino-Ontario, CA	8,900	4	106.00	12	188	61
Bridgeport-Stamford-Norwalk, CT	625	122	106.00	12	234	84
Tampa-St. Petersburg-Clearwater, FL	2,513	55	106.00	12	202	67
Boise City, ID	11,766	2	106.00	12	147	24
Los Angeles County, CA	2,232	65	106.00	12	202	67
New Haven-Milford, CT	605	123	106.00	12	237	87
Boston-Cambridge-Quincy, MA	2,424	59	106.00	12	349	121
Kansas City-Overland Park-Ottawa, KS	2,829	48	106.00	12	275	100
Denver-Aurora-Lakewood, CO	3,906	34	106.00	12	365	123
Chicago-Naperville-Arlington Heights, IL	1,273	103	106.00	12	377	127
Fresno, CA	5,958	13	106.00	12	280	105
Worcester, MA	1,511	95	106.00	12	226	82
Minneapolis-St. Paul-Bloomington, MN	4,731	23	106.00	12	152	30
El Paso, TX	1,013	112	106.00	12	178	52
Austin-Round Rock, TX	4,220	27	106.00	12	143	22
Beaumont-Port Arthur, TX	3,034	46	106.00	12	171	47
Lakeland-Winter Haven, FL	1,798	80	106.00	12	115	10
Deltona-Daytona Beach-Ormond Beach, FL	1,586	87	106.00	12	123	13
Silver Spring-Rockville-Bethesda, MD	1,152	105	106.00	12	132	16
Atlanta-Sandy Springs-Roswell, GA	7,275	9	106.00	12	236	86
Columbia, SC	3,250	43	106.00	12	186	58

TABLE 31—MAXIMUM BID AMOUNTS FOR HCPCS CODE E1390—Continued

[Oxygen concentrator and portable contents/tanks]

Area name	Size in square miles	Size rank	Maximum winning bid E1390	Max E1390 bid rank	Average E1390 services per supplier [1]	Volume rank (low to high) E1390
Memphis, TN	1,926	74	106.00	12	297	111
Omaha, NE	2,265	63	106.00	12	170	46
Council Bluffs, IA	2,085	70	106.00	12	148	26
Oklahoma City, OK	5,512	15	106.00	12	286	106
Chattanooga, TN	1,306	99	106.00	12	176	51
Washington, DC	61	130	106.00	12	113	9
Jacksonville, FL	3,201	45	106.00	12	187	59
Jackson, MS	4,649	24	106.00	12	150	27
Baton Rouge, LA	4,027	32	106.00	12	166	39
South Haven-Olive Branch, MS	2,448	57	106.00	12	214	74
East St. Louis, IL	3,845	36	106.00	12	258	92
Pittsburgh, PA	5,282	16	106.00	12	327	120
Charleston-North Charleston, SC	2,588	54	106.00	12	153	31
Aiken-Edgefield Counties, SC	1,571	90	106.00	12	96	3
St. Louis, MO	5,267	18	106.00	12	315	115
Nassau Kings Queens-Richmond Counties, NY	522	126	106.00	12	216	75
Palm Bay-Melbourne-Titusville, FL	1,016	111	106.00	12	157	34
Rockingham-Strafford Counties, NH	1,064	107	106.00	12	197	64
Milwaukee-Waukesha-West Allis, WI	1,455	96	106.00	12	268	99
Providence, RI	1,034	109	106.00	12	221	77
Huntington, WV	1,570	92	106.00	12	223	80
Dearborn Franklin Ohio-Union Counties, IN	937	113	106.00	12	106	5
Aurora-Elgin-Joliet, IL	2,727	50	106.00	12	191	62
Houston-The Woodlands-Sugar Land, TX	8,827	5	106.00	12	207	69
Tulsa, OK	6,269	11	106.00	12	226	82
Visalia-Porterville, CA	3,377	41	106.00	12	398	128
San Francisco-Oakland-Hayward, CA	2,471	56	106.00	12	166	39
San Jose-Sunnyvale-Santa Clara, CA	2,679	53	106.00	12	130	15
San Diego-Carlsbad, CA	4,207	28	106.00	12	159	35
Cleveland-Elyria, OH	1,997	72	106.00	12	407	129
New Orleans-Metairie, LA	2,422	60	106.00	12	160	36
Pierce-St. Croix Counties, WI	1,296	101	106.00	12	72	1
Dayton, OH	1,706	83	106.00	12	235	85
Cincinnati, OH	2,216	66	106.00	12	311	112
Albany-Schenectady-Troy, NY	2,812	49	106.00	12	263	94
Columbus, OH	4,797	22	106.00	12	199	65
Dallas-Fort Worth-Arlington, TX	9,091	3	106.00	12	262	93
Baltimore-Columbia-Towson, MD	2,948	47	106.00	12	324	118
Bakersfield, CA	8,132	6	106.00	12	164	38
Calvert-Charles-Prince Georges Counties, MD	1,154	104	106.00	12	178	52
Suffolk County, NY	912	114	106.00	12	208	70
Port Chester-White Plains-Yonkers, NY	834	116	106.00	12	153	31
Philadelphia, PA	2,156	67	106.00	12	326	119
Buffalo-Cheektowaga-Niagara Falls, NY	1,565	93	106.00	12	286	106
Rochester, NY	3,266	42	106.00	12	171	47
Detroit-Warren-Dearborn, MI	3,888	35	106.00	12	322	117
Grand Rapids-Wyoming, MI	4,053	31	106.00	12	183	54
Arlington-Alexandria-Reston, VA	3,226	44	106.00	12	166	39
Richmond, VA	4,897	21	106.00	12	275	100
Sacramento-Roseville-Arden-Arcade, CA	5,094	19	106.00	12	210	72
Orange County, CA	791	117	106.00	12	134	18
Oxnard-Thousand Oaks-Ventura, CA	1,290	102	106.00	12	140	20
San Antonio-New Braunfels, TX	7,313	8	106.00	12	210	72
Bronx-Manhattan, NY	65	129	106.00	12	97	4
Virginia Beach-Norfolk-Newport News, VA	2,089	69	106.00	12	253	91
Covington-Florence-Newport, KY	1,400	97	106.00	12	167	42
Lake-McHenry Counties, IL	1,047	108	106.00	12	183	55
Kenosha County, WI	272	128	106.00	12	161	37
Bristol County, MA	553	125	106.00	12	264	97
Springfield, MA	1,844	78	106.00	12	252	90
Tucson, AZ	3,675	38	106.00	12	141	21
Vancouver, WA	2,285	62	106.00	12	121	11
Raleigh, NC	2,118	68	105.00	105	127	14
Asheville, NC	2,033	71	94.00	106	312	114

TABLE 31—MAXIMUM BID AMOUNTS FOR HCPCS CODE E1390—Continued

[Oxygen concentrator and portable contents/tanks]

Area name	Size in square miles	Size rank	Maximum winning bid E1390	Max E1390 bid rank	Average E1390 services per supplier [1]	Volume rank (low to high) E1390
Honolulu, HI	601	124	92.66	107	107	6
Las Vegas-Henderson-Paradise, NV	1,578	89	92.27	108	191	62
Orlando-Kissimmee-Sanford, FL	3,478	40	92.00	109	175	50
Greensboro-High Point, NC	1,994	73	86.84	110	169	45
Poughkeepsie-Newburgh-Middletown, NY	1,607	86	85.35	111	147	24
Augusta-Richmond County, GA	1,909	76	85.00	112	155	33
Allentown-Bethlehem-Easton, PA	1,096	106	85.00	112	263	94
Flint, MI	637	121	84.29	114	150	27
Greenville-Anderson-Mauldin, SC	2,711	51	83.44	115	263	94
Chester Lancaster-York Counties, SC	1,810	79	83.44	115	150	27
Scranton-Wilkes-Barre-Hazleton, PA	1,747	81	83.00	117	311	112
Louisville-Jefferson County, KY	2,440	58	83.00	117	373	125
Little Rock-North Little Rock-Conway, AR	4,085	30	83.00	117	279	103
Stockton-Lodi, CA	1,391	98	82.15	120	122	12
Wilmington, DE	426	127	82.00	121	209	71
Mercer County, PA	673	120	82.00	121	143	22
Jersey City-Newark, NJ	1,926	74	82.00	121	237	87
Camden, NJ	1,674	84	82.00	121	287	108
Youngstown-Warren-Boardman, OH	1,030	110	81.41	125	187	59
Akron, OH	900	115	81.41	125	167	42
Syracuse, NY	2,385	61	81.00	127	265	98
Elizabeth-Lakewood-New Brunswick, NJ	2,239	64	81.00	127	296	110
Catoosa Dade-Walker Counties, GA	783	119	79.80	129	221	77
Toledo, OH	1,618	85	79.80	129	183	55

[1] 2016 allowed services.

Again, we found no correlation between area size and/or average volume for E1390 per supplier and maximum bid amounts. In addition, CBAs that had the highest maximum winning bids for code E0260 did not always have the highest maximum winning bids for code E1390. For example, the Cape Coral-Fort Myers, Florida CBA had the highest maximum winning bid for E1390, but was tied for the 55th highest maximum winning bid for E0260. In many cases, national chain suppliers for oxygen bid the same amount in every area. For oxygen and oxygen equipment (E1390), there were six national chain suppliers that submitted the same winning bid amounts in at least 33 different CBAs and four suppliers that submitted the same winning bid amounts in at least 67 different CBAs. One of these suppliers submitted the maximum winning bid for E1390 of $106 in 93 different CBAs.

Maximum bid amounts can be bid amounts from a single supplier (the supplier submitting the pivotal bid), which may or may not reflect the costs of other suppliers and don't seem to show any pattern from area to area in terms of some areas always having the highest maximum bids for items and other areas always having the lowest maximum winning bids for items. The maximum winning bids for items show no correlation with area size, volume, or number of suppliers. In some cases, the maximum bid amount is the same in dozens of different CBAs across the country. The maximum bids for lower weight items are also impacted by unbalanced bidding, whereby the suppliers bid higher amounts for these items knowing that they will have little impact on their composite bid and chances for winning.

3. Travel Distance Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the average travel distances associated with furnishing items and services in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We first examined the average travel distances in CBAs versus non-CBAs by analyzing differences in the geographic size in square miles of CBAs versus non-CBAs consisting of MSAs and micropolitan statistical areas (micro areas). The majority of items subject to the fee schedule adjustments are furnished in these non-CBAs.

The U.S. Office of Management and Budget (OMB) delineates MSAs and micro areas, which are referred to collectively as ''core based statistical areas'' (CBSAs). OMB set the standards for delineating MSAs and micro areas in the notice published on June 28, 2010 in the **Federal Register**, titled ''2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas'' (75 FR 37245). The general concept of the MSA and micro area is that of a core area containing a substantial population nucleus, together with adjacent communities having a higher degree of economic and social integration with that core. CBSAs consist of counties and equivalent entities throughout the U.S. and Puerto Rico (75 FR 37249). A CBSA is categorized based on the population of the largest urban area (urbanized area or urban cluster) within the CBSA (75 FR 37250). Each CBSA must have a Census Bureau delineated urbanized area of at least 50,000 population or a Census Bureau delineated urban cluster of at least 10,000 population (75 FR 37249). An urbanized area is a statistical geographic entity delineated by the U.S. Census Bureau, consisting of densely settled census tracts and blocks and adjacent densely settled territory that together contain at least 50,000 people (75 FR 37252). An urban cluster is a statistical geographic entity delineated by the U.S. Census Bureau, consisting of densely settled census tracts and blocks and adjacent densely settled territory that together contain at least 2,500

people (75 FR 37252). MSAs contain at least one urbanized area that has a population of at least 50,000; micro areas contain at least one urban cluster that has a population of at least 10,000 and less than 50,000 (75 FR 37252).

We compared the average size of the different areas nationally and by Bureau of Economic Analysis (BEA) region. We also computed the weighted average size of the different areas nationally and by region, weighted by total population. The CBAs have much larger service areas than the non-CBA MSA and micro areas. It is also worth noting that our current definition of rural area for the purposes of fee schedule adjustments in non-CBAs includes micro areas (in general, a rural area is currently defined at 42 CFR 414.202 as any zip code area where at least 50 percent of the area is outside a MSA or with a low population density that was excluded from a CBA).

Under the CBP, a contract supplier is required to deliver items to any beneficiary in the CBA that requests service. The size of CBAs can be compared to the size of non-CBAs to indicate how far a supplier located in or near the areas may have to travel to serve beneficiaries located in the various areas. As shown in Table 32, the average size of CBAs in each of the eight BEA regions is larger than the average size of both non-rural areas and rural areas classified as micro areas by OMB, areas where competitive bidding, for the most part, not yet been implemented, and where the vast majority of items are furnished in the non-CBAs.

TABLE 32—AVERAGE SIZE OF AREA

[Square miles]

BEA region	CBA	MSA	Micro
New England	1,241	1,175	968
Mideast	1,659	833	859
Great Lakes	2,061	942	638
Plains	3,700	1,880	1,029
Southeast	2,776	1,218	681
Southwest	5,737	3,637	1,992
Rocky Mountain	6,457	3,025	3,002
Far West	3,791	2,308	3,776
Average	3,428	1,877	1,618

The average non-CBA MSA size is 55 percent of the average CBA size and the average non-CBA micro area size is 47 percent of the average CBA size. As shown in Table 33, when weighting the average size of the areas based on U.S. Census total resident 2010 population numbers, the differences in the average size of the areas is similar to the differences noted in Table 32. The weighted average non-CBA MSA size is 57 percent of the weighted average CBA size and the weighted average non-CBA micro area size is 43 percent of the weighted average CBA size.

TABLE 33—AVERAGE SIZE OF AREA (SQUARE MILES) WEIGHTED BY POPULATION

BEA region	CBA	MSA	Micro
BEA Region	CBA	MSA	Micro
New England	1,624	1,273	1,094
Mideast	1,718	937	1,016
Great Lakes	2,707	1,875	711
Plains	4,371	3,169	1,157
Southeast	5,780	1,517	911
Southwest	7,917	3,510	2,355
Rocky Mountain	5,559	3,934	3,494
Far West	3,833	2,749	3,582
Average	4,189	2,371	1,790

The size of the CBAs are much larger than the size of the non-CBA MSAs and micro areas where most of the items subject to the fee schedule adjustments are furnished. The contract suppliers must serve every part of these areas and have much larger travel distances on average than suppliers in both non-CBA urban areas (MSAs) and non-CBA rural areas (areas outside MSAs).

The data in Table 34 shows what percentage of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where the items and services are furnished (that is, the percentage of suppliers located in the same area as the beneficiary). We separated the data by CBA, and then non-CBA MSA, micro area, or Outside Core Based Statistical Area (OCBSA), which are counties that do not qualify for inclusion in a CBSA. The data in Table 34 shows that the majority of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where these items and services are furnished.

TABLE 34—PERCENTAGE OF ITEMS AND SERVICES IN 2016 FURNISHED BY SUPPLIERS LOCATED IN THE SAME AREA AS THE BENEFICIARY

Beneficiary area	Hospital beds (%)	Oxygen (%)	All items (%)
CBAs	68	77	64

TABLE 34—PERCENTAGE OF ITEMS AND SERVICES IN 2016 FURNISHED BY SUPPLIERS—Continued LOCATED IN THE SAME AREA AS THE BENEFICIARY

Beneficiary area	Hospital beds (%)	Oxygen (%)	All items (%)
Non-CBA MSAs	68	63	65
Non-CBA Micro Areas	64	61	61
Non-CBA OCBSAs	78	82	81

We also compared the average travel distances for suppliers in the different areas using claims data for items and services subject to the fee schedule adjustments. For each allowed DME item and service, we used the shortest distance between the coordinates of the beneficiary's residential ZIP code and those of the supplier's ZIP code on the surface of a globe as a proxy of DME delivery distance. In addition, we prioritized 9-digit ZIP codes over 5-digit ZIP codes when determining the coordinates. The results in Table 35 are for hospital beds and oxygen and oxygen equipment, items that are most likely to be delivered locally by suppliers using company vehicles.

TABLE 35—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON CLAIMS FOR 2016

Beneficiary area	Hospital beds	Oxygen
CBAs	62	79
Non-CBA MSAs	35	54
Non-CBA Micro Areas	30	49
Non-CBA OCBSAs	34	57

These results indicate that the average travel distances in CBAs are much greater than the average travel distances in all non-CBAs, but the data may be skewed by claims for suppliers that put a billing address on the claim that is not the address of the location that furnished the item (either a different location or a subcontractor). The data may also be skewed by claims where the beneficiary receives the item from a supplier in a different area because he or she is travelling (for example, ''snowbirds''). To account for this, we excluded data for claims where the beneficiary address was more than two states away from the supplier location on the claim form, as these are likely claims where the item was delivered from a different location or by a sub-contractor, or were claims for traveling beneficiaries (that is, snowbirds and other beneficiaries receiving items from suppliers in locations other than their permanent residence). We also excluded data for suppliers with multiple locations that always put the same address on all of their claims. When using data for this restricted population (beneficiaries receiving items from suppliers in same or adjoining states) and these restricted suppliers (all suppliers except those with multiple locations that always bill from the same location), the results on average distances are significant, as shown in Table 36 for hospital beds, oxygen and oxygen equipment, and all items subject to the fee schedule adjustments.

TABLE 36—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON RESTRICTED CLAIMS FOR 2016 [1]

Beneficiary area	Hospital beds	Oxygen	All items
CBAs	25	21	27
Non-CBA MSAs	22	19	24
Non-CBA Micro Areas	23	21	27
Non-CBA OCBSAs	27	30	36

[1] Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

Based on these results, the average distances from the supplier to the beneficiary in the CBAs are still greater than the average distances from the supplier to the beneficiary in the non-CBA MSAs and micro areas where most of the items subject to the fee schedule adjustments are furnished. However, the average distances for other rural areas (areas outside both MSAs and micro areas) are slightly greater than the average distances for the CBAs.

It is not surprising that the average distances between supplier billing locations and beneficiary residences are greater in CBAs than in non-CBA MSAs and micro areas given the findings above that the CBAs are much larger areas and given that the majority of items furnished in the various areas are furnished by suppliers located in those areas. Regardless of the type of area, it makes sense that suppliers would locate their businesses in the places where most of the population resides (cities and towns). The means that the average distance travelled by the supplier will be weighted heavily in favor of the shorter trips made from the location to the beneficiaries living in the immediate area. The supplier will also make much longer trips, but these trips would not have as great an impact on the average travel distance as the trips made to the population nucleus immediately surrounding the supplier location.

We also did this same analysis comparing average distances in CBAs versus non-CBAs broken out not based on whether the beneficiary resided in an MSA, micro area, or OCBSA, but broken out based on whether or not the

beneficiary resided in a super rural (SR) area based on the definition of super rural area used in the ambulance fee schedule rules in § 414.610(c)(5)(ii). Specifically, we used the April 2018 quarterly Zip Code to Carrier Locality File. When doing so, we found that out of all allowed services for DME items subject to the fee schedule adjustments, 9 percent of allowed services were furnished in SR areas. From 2015 to 2016, SR areas saw a 3 percent increase in allowed services. At the product category level, SR areas exhibit the same level of change in service volume as the rest of the nation. Without any data restrictions, CBAs tend to have greater average service distances than non-CBAs. For the restricted population, however, SR areas almost always show the greatest average distance. Lastly, we did not find any noticeable increase in service distance from 2015 to 2016 for any product category.

Table 37 shows the data for claims from all suppliers and Table 38 shows the data for the same restricted claims.

TABLE 37—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON CLAIMS FOR 2016

Beneficiary area	Hospital beds	Oxygen
CBAs	62	79
Non-SR Areas	32	51
SR Areas	48	64

TABLE 38—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON RESTRICTED CLAIMS FOR 2016 [1]

Beneficiary area	Hospital beds	Oxygen	All items
CBAs	25	21	27
Non-SR Areas	22	19	25
SR Areas	36	35	41

[1] Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

We also did this same analysis comparing average distances in CBAs versus non-CBAs broken out not based on whether the beneficiary resided in an MSA, micro area, or OCBSA, but broken out based on whether or not the beneficiary resided in a far and remote (FAR) area. We examined whether the beneficiary resided in a FAR area, as defined by the Office of Rural Health Policy in the Health Resources and Services Administration in a final notice published on May 5, 2014 in the **Federal Register**, titled ''Methodology for Designation of Frontier and Remote Areas'' (79 FR 25599). FAR is a statistical delineation that defines frontier and remote areas based on remoteness and population sparseness. FAR areas are defined in relation to the time it takes to travel by car to the edges of nearby Census defined Urban Areas. The Department of Agriculture maintains a list of ZIP codes that identify FAR areas in the U.S. Specifically, we used the 2010 Frontier and Remote Area Codes Data Files, last updated by the Department of Agriculture on April 15, 2015.[18] There are four levels of FAR, as rural areas experience degrees of remoteness at higher or lower population levels that affect access to different types of goods and services.

We looked at whether the beneficiary resided in a FAR level 1 (FAR1) area: An area with a population of less than 50,000 people located 60 minutes or more from an area with a population of at least 50,000 people. Roughly 7 percent of items and services subject to competitive bidding nationally are furnished in these FAR1 areas.

We also compared average distances in CBAs versus non-CBAs broken out based on whether the beneficiary resided in a FAR level 3 (FAR3) area: An area with a population of less than 10,000 people located 30 minutes or more from an urban area of 10,000 to 24,999 people, 45 minutes or more from an urban area of 25,000 to 49,999 people, and 60 minutes or more from an urban area of 50,000 or more. Roughly 3 percent of items and services subject to competitive bidding nationally are furnished in these FAR3 areas.

Table 39 shows the data for claims from all suppliers and Table 40 shows the data for the same restricted claims.

TABLE 39—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON CLAIMS FOR 2016

Beneficiary area	Hospital beds	Oxygen
CBAs	62	79
Non-FAR Areas	33	52
FAR1 Areas	40	57
FAR3 Areas	49	72

TABLE 40—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON RESTRICTED CLAIMS FOR 2016 [1]

Beneficiary area	Hospital beds	Oxygen	All items
CBAs	25	21	27

[18] *https://www.ers.usda.gov/data-products/frontier-and-remote-area-codes/.*

TABLE 40—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY—Continued BASED ON RESTRICTED CLAIMS FOR 2016 [1]

Beneficiary area	Hospital beds	Oxygen	All items
Non-FAR Areas	22	20	26
FAR1 Areas	29	30	37
FAR3 Areas	37	40	46

[1] Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

Average distances between suppliers and beneficiaries in areas falling under the current definition of rural areas at § 414.202 are not greater than the average distances in CBAs. When the restricted data for rural areas for non-CBAs is broken out by micro area and OCBSA, the distances are only slightly greater for OCBSAs than CBAs. However, when the restricted data for non-CBAs in general is broken out based on whether the non-CBA is a FAR3, Super Rural, or OCBSA, the distances between suppliers and beneficiaries are much greater than for the CBAs.

4. Cost Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the average costs associated with furnishing items and services in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. In our CY 2015 ESRD PPS proposed rule published in the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies;'' (79 FR 40279), we noted that Congress previously mandated that the costs of furnishing DME in different geographic regions of the country be studied. Section 135 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), required an examination of the geographic variations in DME supplier costs in order to determine whether the fee schedules are reasonably adjusted to account for any geographic differences. Jing Xing Health and Safety Resources, Inc. provided assistance to the Health Care Financing Administration, now CMS, in conducting this study. The project, titled ''Durable Medical Equipment Supplier Product and Service Cost Study'', was completed under Contract Number Health Care Financing Administration (HCFA) 500–95–0044 and submitted to the agency in June 1996.[19] As part of the study, a Federal Advisory Panel was convened, a formal meeting with representatives of the DME industry was held, and a literature review was conducted. The general consensus among industry representatives and government agencies that participated in the study was that there is no conclusive evidence that urban and rural costs differed significantly or that the costs of furnishing DME items and services were higher in urban areas versus rural areas or vice versa.

Jing Xing Health and Safety Resources, Inc. summarized the findings from the study in a report titled ''Final Report: Durable Medical Equipment Supplier Product and Service Cost Study'', and stated that, ''At one level, it is intuitively obvious that certain DME categories require a much larger service component than others. To illustrate, the service component in providing oxygen equipment is a larger proportion of costs than, for example, selling a walker or cane. The latter does not involve very much, if any, assembly, patient education, maintenance, etc.'' Additionally, ''There was a general consensus among study participants that excluding the impact of volume purchasing the costs of acquiring DME items (that is, wholesale costs) are generally the same around the country with the possible exceptions of Alaska and Hawaii where shipping costs are greater. There was also general agreement that service costs do vary with the largest geographic variation resulting from labor costs. Limited tests using Medicare data provide support for the theory that geographic variation in the costs of providing DME is primarily caused by service components.''

In researching cost data for section 16008 of the Cures Act, we sought data that was national in scope, robust, and would allow us to access differences in costs of furnishing items and services in CBAs versus non-CBAs throughout the country. We also primarily sought data that was available at the county level, as this allowed us to compare CBA counties to non-CBA counties. CBAs are currently comprised of whole counties, except when certain low population density areas are excluded from a county included in a CBA in accordance with section 1847(a)(3)(A) of the Act.

We examined four sources of cost data: (1) The Practice Expense Geographic Practice Cost Index (PE GPCI), (2) delivery driver wages from the Bureau of Labor Statistics (BLS), (3) real estate taxes from the U.S. Census Bureau's American Community Survey (ACS), and (4) gas and utility prices from the Consumer Price Index (CPI). Overall, we found that CBAs tended to have the highest costs out of the cost data that we examined, when compared to non-CBAs. We will now discuss the cost data sources we examined, and the methodology we used to analyze such cost data.

a. Cost Data Methodology

We first examined the PE GPCI. CMS first implemented the GPCIs as part of the Medicare Physician Fee Schedule (PFS) in 1992 (56 FR 59502). CMS must review and, if necessary, adjust the GPCIs at least every 3 years, as required by section 1848(e)(1)(C) of the Act. The most recent update occurred in 2017, in which a final rule was published on November 15, 2016 in the **Federal Register**, titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' (81 FR 80170). The PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and medical equipment, supplies and other miscellaneous expenses), and are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the 89 PFS fee schedule areas

[19] *https://ia800903.us.archive.org/14/items/durablemedicaleq00kowa/durablemedicaleq00kowa.pdf.*

throughout the nation, as compared to the national average of these costs. The current 89 fee schedule areas are defined by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS (81 FR 80263).

The employee wage index measures several kinds of wages for clinical and administrative office staff. The current GPCI methodology relies on wage data from occupations representing 100 percent of total non-physician wages in the ''offices of physicians: industry'' from the BLS Occupational Employment Statistics (OES). This includes wages for ''Medical secretaries,'' ''Receptionists and information clerks,'' ''Medical records and health information technicians,'' and other additional occupations.[20]

The purchased services index includes BLS OES wages for occupations employed in industries from which physicians are likely to purchase services, which includes the cost of contracted services (for example, accounting, legal). This includes wages for ''Commercial and industrial machinery and equipment repair and maintenance,'' ''Services to buildings and dwellings,'' and other additional occupations.[20]

The office rent index measures regional variation in the price of office rents using residential rent data from the U.S. Census Bureau's American Community Survey (ACS) on median gross rents for two-bedroom apartments. The ACS determines gross rent by adding up the following: Contract rent + utilities (electricity, gas, and water and sewer) + fuel (oil, coal, kerosene, wood, etc.). As such, we are using the PE GPCI as a proxy for commercial rent and utilities.

In a final rule published on November 15, 2016 in the **Federal Register**, titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' final rule (81 FR 80170), we stated because Medicare is a national program, and section 1848(e)(1)(A) of the Act requires CMS to establish GPCIs to measure relative cost differences among localities compared to the national average, we believe it is important to use the best data that is available on a nationwide basis, that is regularly updated, and retains consistency area-to-area, year-to-year (81 FR 80263). CMS discussed how there is currently no national data source available for physician office or other comparable commercial rents, which is why CMS uses county-level residential rent data from ACS as a proxy for the relative cost differences in commercial office rents. The ACS is administered by the U.S. Census Bureau, which is a leading source of national, robust, quality, publicly available data. A commercial data source for office rent that provided for adequate representation of urban and rural areas nationally would be preferable to a residential rent proxy. The GPCIs are not an absolute measure of practice costs, rather they are a measure of the relative cost differences for each of the three GPCI components. The U.S. Census Bureau is a federal agency that specializes in data collection, accuracy, and reliability, and we believe that where such a publicly available resource exists that can provide useful data to assess geographic cost differences in office rent, even though it is a proxy for the exact data we seek, we should utilize that available resource.

Therefore, given its national representation, reliability, high response rate and frequent updates, we believe the ACS residential rent data is the most appropriate data source available at this time for the purposes of analyzing rent and utilities. It is also worth noting that we examine utility prices from the CPI as another source of cost data, which is discussed further on in the preamble of this proposed rule.

The medical equipment, supplies and other miscellaneous expense cost index component of the PE GPCI measures practice expenses associated with a wide range of costs that include chemicals and rubber, to telephone and postage. The medical equipment, supplies, and miscellaneous expenses index holds that there is a national market for the items it measures such that there is not significant geographic variation in costs. Therefore, this index is given a value of 1.000 for each PFS fee schedule area. We discussed our reasoning behind this in the final rule published on November 15, 2004 in the **Federal Register**, titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005'' (69 FR 66235), stating ''We were again unable to find any data sources that demonstrated price differences by geographic areas. As mentioned in previous updates, some price differences may exist, but these differences are more likely to be based on volume discounts rather than on geographic areas.'' Separately billable items such as DMEPOS are generally not included in this index, but this finding is consistent with the aforesaid findings from the Jing Xing Health and Safety Resources, Inc. study.

The PE GPCIs are calculated at the fee schedule area level after aggregating the county-level component indexes. The PE GPCI county level data are for informational purposes only so that interested parties can have a better understanding of the data that underpin their fee schedule area GPCI values. In order to compare CBAs and non-CBAs, we used CY 2017 PE GPCI county data (CY 2017 PFS final rule (81 FR 80170)) found in the GPCI public use files.[21] This allowed us to then map each county in this dataset to either a CBA, or non-CBA by MSA, micro area, or OCBSA county, and to then see its corresponding PE GPCI. The counties and county equivalent names listed in this file are from the 2010 U.S. Census.

When mapping counties to CBAs, we selected all counties that were included in Round 2 Recompete or Round 1 2017. We then used OMB Bulletin No. 15–01 as the source for mapping the remaining counties to either non-CBA by MSAs, micro areas, or OCBSAs.[22] After doing this, we grouped all contiguous counties of the U.S. with the same delineation and BEA Region together. We grouped any non-contiguous counties of the U.S. with the same delineation together. We then calculated the weighted average of each delineation's PE GPCI value using U.S. Census 2010 total resident population numbers for each county. For this PE GPCI analysis, we included all 50 states and the District of Columbia.

Although counties in Puerto Rico and the Virgin Islands have a PE GPCI value, each is assigned the GPCI national average of 1.0. For the Virgin Islands, because county-level wage and rent data are not available, and insufficient malpractice premium data are available, CMS has set the PE GPCI values for the

[20] Proposed Revisions to the Sixth Update of the Geographic Practice Cost Index. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CMS_1524_P_CY2012_PFS_NPRM_GPCI_Revisions.pdf.*

[21] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1654-F.html.*

[22] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf.*

Virgin Islands fee schedule area at the national average of 1.0 (81 FR 80269). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the states in accurately accounting for variability of costs for these island territories, we discussed in a final rule published on November 15, 2016 in the **Federal Register**, titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' final rule (81 FR 80170) that we would treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We thus finalized a proposal to do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. Thus, in calculating weighted average PE GPCIs for non-contiguous areas, we only incorporated PE GPCIs from Hawaii and Alaska.

Because stakeholders on the March 23, 2017 stakeholder call indicated that deliveries make up a significant part of the costs when furnishing items and services, we examined delivery driver wages as the next source of cost data. The BLS OES provides delivery driver wage data in the ''53–0000 Transportation and Material Moving Occupations'' occupation group. Specifically, we used the ''53–3033 Light Truck or Delivery Services Drivers'' individual occupation wage index, which is underneath the ''53–0000 Transportation and Material Moving Occupations'' occupation group.

We used the median hourly wage from the ''53–3033 Light Truck or Delivery Services Drivers'' individual occupation wage index as the source of this delivery driver wage data. We used median hourly wage values from the May 2016 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates.[23]

For this analysis, we used a similar methodology that we used for the aforesaid PE GPCI analysis. We mapped each county to two areas: Its corresponding delineation (CBA, non-CBA MSA, non-CBA micro area, or non-CBA OCBSA), and its BEA Region. We then mapped counties to their corresponding median hourly wage by using the May 2016 Metropolitan and Nonmetropolitan Area Definitions provided by the BLS.[24] In cases where BLS did not have a median hourly delivery driver wage for a particular county, we calculated and then assigned such counties the median hourly delivery driver wage for that county's state (this was the case for the following counties: Bradley County, Tennessee (TN); Polk County, TN; Los Alamos County, New Mexico; Champaign County, Illinois (IL); Piatt County, IL; Ford County, IL; Kankakee County, IL). In order to come up with an hourly wage for each BEA Region and delineation, we calculated the weighted average of the median hourly wages for the counties within each area, basing the weighted average off of each county's U.S. Census total resident 2010 population numbers.

For New England states, the BLS assigns wages to New England city and town areas (NECTAs) instead of metropolitan and non-metropolitan areas that adhere to county boundaries, which the BLS does for every other area outside of New England. An issue with assigning wages to NECTAs is that there is not a one-to-one mapping of NECTAs to counties, as the collection of townships in a NECTA may not completely cover a county. This results in counties being represented in multiple NECTAs. To address this issue, we mapped NECTAs to New England counties by using the U.S. Census Bureau's ''NECTAs, NECTA divisions, and combined NECTAs'' file that is based on OMB Bulletin No. 15–01 delineations.[25] If a New England county had more than one NECTA, we calculated the weighted average of each of its NECTAs' median hourly wages. We used total population estimates from the 2016 ACS for the population weighting (U.S. Census Bureau, 2012–2016 ACS 5-Year Estimates).

OMB set the standards for NECTAs in the notice published on June 28, 2010 in the **Federal Register**, titled ''2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas'' (75 FR 37245). Based upon these standards, 10 counties in New England did not have any towns or cities that qualified as NECTAs (Aroostook County, Maine (ME); Caledonia County, Vermont (VT); Carroll County, New Hampshire; Essex County, VT; Franklin County, ME; Knox County, ME; Nantucket County, Massachusetts; Orleans County, VT; Washington County, ME; and Windham County, (VT). We assigned delivery driver wages to these 10 counties based upon which area each of these counties' seat were located in the May 2016 Metropolitan and Nonmetropolitan Area Definitions provided by BLS.[26]

We also used ACS data to examine real estate taxes. We analyzed 2016 data from the survey titled ''Mortgage Status by Median Real Estate Taxes Paid (Dollars) Universe: Owner-occupied housing units''.[27] In this survey, ACS provides a median real estate tax for each U.S. county, thus allowing us to use a similar methodology that we used for the PE GCPIs and delivery driver wages. In order to come up with a real estate tax value for each BEA Region and delineation, we calculated the weighted average of the median real estate tax values for the counties within each area, basing the weighted average off of each county's U.S. Census total resident 2010 population numbers. It is worth noting that the ACS measures real estate taxes paid on housing units, not business units. However, similar to our reasoning above for using residential rent data provided by the ACS as a proxy for commercial rent, we believe the ACS is a valuable tool in measuring geographic differences in cost, and are also using real estate taxes on housing units as a proxy to measure taxes paid on business units.

In order to further examine costs, we also analyzed CPI data for gas and utility prices. For each month in 2016, BLS released a CPI detailed report with monthly prices for various data included in the CPI.[28] In order to analyze gas prices, we compiled the CPI detailed report for every month in 2016, and calculated the annual average for the values in the ''Gasoline All Types'' index of ''Table P3: Average prices for gasoline, U.S. city average and selected areas'' of the CPI detailed report. In order to analyze utility prices, we compiled the CPI detailed report for every month in 2016, and calculated the annual average for the values in ''Table P2: Average residential unit prices and consumption ranges for utility (piped) gas and electricity for U.S. city average and selected areas''. Specifically, we looked at the ''Average price per therm of utility (piped) gas'' and the ''Average price per KWH of electricity'' index in the CPI report. As discussed earlier in the preamble of this proposed rule, the Office Rent Index of the PE GPCI

[23] *https://www.bls.gov/oes/tables.htm.*

[24] *https://www.bls.gov/oes/current/msa_def.htm.*

[25] *https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html.*

[26] NACo Analysis of U.S. Census Bureau, NACo Research, 2013.

[27] U.S. Census Bureau, 2012–2016 American Community Survey 5-Year Estimates.

[28] *https://www.bls.gov/cpi/cpi_dr.htm.*

already includes utilities in its calculation, based on ACS residential rent data. Nevertheless, we examined an additional source of utility prices, in order to further examine any potential price trends.

BLS separates prices in these tables based upon the following size classes: A, B/C, and D. Size A represents metropolitan areas with a population of over 1,500,000, size B/C represents mid-sized and small metropolitan areas (population of 50,000 to 1,500,000), and size D represents nonmetropolitan urban areas.[29]

An issue with CPI size classes is that the CPI data cannot directly map to every county and BEA Region in the U.S., unlike the previously discussed cost data. This is because the CPI data is only available at the national level, for a select number of metropolitan areas, and for the four U.S. Census Bureau Regions.

However, the CPI sampled a total of 87 Primary Sampling Units (PSUs) for the 2016 CPI, which are the smallest geographic areas in which pricing is done for the CPI. Appendix 4 in Chapter 17 of the BLS Handbook of Methods lists the 87 PSUs sampled in the 2016 CPI.[30] Appendix 4 also lists the counties in these PSUs that the CPI sampled, which totaled 425 counties and included counties in the contiguous and non-contiguous U.S.

We found that CBA counties made up the majority of size class A and B/C, while non-CBA micro and OCBSA counties made up the majority of size class D. The exact number can be found in Table 41, and the exact percentages can be found in Table 42. In order to identify the delineation of these counties and to be consistent with our previous cost data analyses, we used the same reference materials that we used for our previous cost data analyses: county and county equivalent names from the 2010 U.S. Census, and county and county equivalent delineations from OMB Bulletin No. 15–01.

It is worth noting that although the CPI data is from 2016, the 2016 CPI bases the counties and county equivalents and their size classes off of the 1990 decennial Census and its Metropolitan Areas off of OMB Bulletin No. 93–05.[31] One implication of this is that counties and county equivalents sampled in the 2016 CPI may have changed size classes based upon their population numbers in the 2010 Census, and their Metropolitan Area status in OMB Bulletin No. 15–01. Further, CBSAs, micro areas, and OCBSAs were not a concept at the time in OMB Bulletin No. 93–05. Additionally, the counties and county equivalents that the CPI sampled were based off of the 1990 U.S. Census, meaning that the CPI data would not reflect any substantial changes to counties and county equivalent entities after 1990, as indicated by the U.S. Census Bureau.[32] However, most of the county and county equivalent names that the CPI sampled remained the same or were similar to those in the 2010 U.S. Census, allowing us to map the counties and county equivalents listed in Appendix 4 of Chapter 17 of the BLS Handbook of Methods to those in the 2010 U.S. Census. We also believe that this CPI data is a valuable tool in examining price trends for gas and utilities amongst differently sized areas with varying levels of urbanization. Further, because we are able to know which counties the CPI sampled, we are able to know which size classes have CBA and non-CBA counties, thus allowing us to compare costs between CBAs and non-CBAs, making it useful for our data purposes in fulfilling section 16008 of the Cures Act.

TABLE 41—NUMBER OF COUNTIES SAMPLED IN 2016 CPI

Delineation	Size A	Size B/C	Size D	Total number counties
CBA	235	86	1	322
Non-CBA MSA	26	46	3	75
Non-CBA Micro	5	8	8	21
Non-CBA OCBSA	1	0	6	7
Total number Counties	267	140	18	425

TABLE 42—COUNTY DELINEATION PERCENTAGES FOR 2016 CPI

Delineation	Size A %	Size B/C %	Size D %
CBA	88.01	61.43	5.56
Non-CBA MSA	9.74	32.86	16.67
Non-CBA Micro	1.87	5.71	44.44
Non-CBA OCBSA	0.37	0.00	33.33
Total	100.00	100.00	100.00

b. Cost Data Results

We found that, on average, CBAs had higher costs than non-CBAs, for most of the cost data that we examined. For instance, CBAs had the highest average PE GPCI in every BEA Region, when compared to the non-CBAs in each BEA Region. CBAs had the highest average driver wage in all but one BEA Region (Rocky Mountain), when compared to the non-CBAs in each Region. CBAs also had the highest average real estate tax in every BEA Region, when compared to the non-CBAs in each BEA Region.

Typically, the ranking from highest to lowest cost delineation in each BEA Region was the following: (1) CBA, (2) non-CBA MSA, (3) non-CBA micro, and (4) non-CBA OCBSA. Thus, the more urbanized areas tended to have higher costs than the less urbanized areas.

[29] *https://www.bls.gov/opub/mlr/1996/12/art2full.pdf.*

[30] BLS Handbook of Methods. Chapter 17. The Consumer Price Index. (Updated 06/2015).

[31] *https://www.bls.gov/opub/mlr/1996/12/art2full.pdf.*

[32] *https://www.census.gov/geo/reference/county-changes.html.*

Additionally, we found that BEA Regions have different costs. We arranged the 8 BEA Regions into two cost tiers, for each of the cost data that we examined. The top tier included BEA Regions where costs were, on average, the highest. The bottom tier included BEA Regions where costs were, on average, the lowest. To be in the top tier, a BEA Region had to have a value that was in the top 50 percent of all 8 BEA Region values. To be in the bottom tier, a BEA Region had to have a value that was in the bottom 50 percent of all 8 BEA Region values. Overall, the Far West, Mideast, and New England Regions tended to be in the top cost tier for most of the cost data sources that we examined. The Far West Region was in the top cost tier most often, indicating that its costs are amongst the highest out of the 8 BEA Regions.

The Far West, New England, Mideast, and Rocky Mountain BEA Regions were in the top tier of average PE GPCI values in the 8 BEA Regions. For instance, when looking at the average PE GPCI value for each of the 8 BEA Regions, these 4 BEA Regions' average PE GPCI values were in the top 50 percent for every delineation. The bottom tier included the Great Lakes, Southwest, Plains, and Southeast BEA Regions. They were all in the bottom 50 percent of average PE GPCI values, for every delineation.

When looking at the average delivery driver wage for each of the 8 BEA Regions, the Plains and Far West Regions' average driver wage were in the top 50 percent for every delineation. New England, Mideast, and Rocky Mountain were also a part of this top tier, yet alternated in and out of the top 50 percent, depending on which delineation we examined. The bottom tier for delivery driver wages included the Great Lakes, Southwest, and Southeast BEA Regions.

For real estate taxes, the New England and Mideast BEA Regions had significantly higher real estate taxes, on average, than every other BEA Region, for each delineation. The BEA Regions of New England, Mideast, Far West, and the Great Lakes were in the top 50 percent of real estate taxes for every delineation. The BEA Regions of Southwest, Plains, Southeast, and Rocky Mountain were in the bottom 50 percent of real estate taxes for every delineation.

It is worth noting that we did not include non-contiguous areas in the average values for the 8 BEA Regions, and instead counted non-contiguous areas as their own type of area. In doing so, we found that the average PE GPCI for non-contiguous delineations (in Alaska and Hawaii) were higher than every other delineation in the 8 BEA Regions. Additionally, the average driver wage for non-contiguous delineations (in Alaska and Hawaii), were higher than every other delineation in the 8 BEA Regions, except for non-contiguous micro areas, which were only lower than driver wages in the micro areas of the Rocky Mountain BEA Region. When we included driver wages from Puerto Rico in the non-contiguous average driver wage calculation (along with Alaska and Hawaii), the Puerto Rico driver wages lowered the average non-contiguous driver wages so that OCBSAs were then the only non-contiguous delineation with a higher value than delineations in the 8 BEA Regions.

Lastly, there were certain non-CBA counties around the country that had relatively high driver wages—driver wages that were higher than that of CBA counties. These counties primarily were in the Plains, Rocky Mountain, and Far West BEA Regions. Many of these non-CBA counties with higher driver wages were either OCBSAs or micro areas. However, many other OCBSA or micro counties elsewhere in the country had relatively low driver wages. It is also worth noting that these very same counties that had higher driver wages had relatively low PE GPCI values and real estate taxes.

Table 43 shows the summary of these cost data results.

TABLE 43—AVERAGE COSTS BY BEA REGION

BEA region	Delineation	PE GPCI	Average median driver wage per hour	Annual residential real estate tax
Far West	CBA	1.14	$15.79	$3,463.59
Far West	MSA	1.03	15.11	2,413.43
Far West	Micro	0.96	15.04	1,778.87
Far West	OCBSA	0.96	15.06	1,663.85
Great Lakes	CBA	0.97	14.77	3,338.46
Great Lakes	MSA	0.92	14.08	2,322.51
Great Lakes	Micro	0.87	13.19	1,629.62
Great Lakes	OCBSA	0.86	12.85	1,491.14
Mideast	CBA	1.11	15.92	5,245.05
Mideast	MSA	0.96	13.92	3,132.32
Mideast	Micro	0.89	12.97	2,102.79
Mideast	OCBSA	0.89	13.46	2,208.62
New England	CBA	1.10	16.49	4,725.59
New England	MSA	1.02	14.88	3,739.11
New England	Micro	1.00	14.02	4,065.67
New England	OCBSA	0.93	13.17	2,317.18
Plains	CBA	0.98	16.20	2,408.32
Plains	MSA	0.90	14.45	2,049.21
Plains	Micro	0.87	13.34	1,489.76
Plains	OCBSA	0.84	13.52	1,160.55
Rocky Mountain	CBA	1.00	15.28	1,658.02
Rocky Mountain	MSA	0.93	14.60	1,506.69
Rocky Mountain	Micro	0.93	16.09	1,428.58
Rocky Mountain	OCBSA	0.88	15.64	1,047.09
Southeast	CBA	0.97	14.47	1,821.26
Southeast	MSA	0.90	13.19	1,094.17
Southeast	Micro	0.84	12.38	787.18
Southeast	OCBSA	0.83	12.12	624.88
Southwest	CBA	0.97	14.38	2,643.70

TABLE 43—AVERAGE COSTS BY BEA REGION—Continued

BEA region	Delineation	PE GPCI	Average median driver wage per hour	Annual residential real estate tax
Southwest	MSA	0.91	13.42	1,698.48
Southwest	Micro	0.87	12.96	1,054.82
Southwest	OCBSA	0.85	12.66	915.76

Tables 44 through 46 summarize the data at the national contiguous level and for non-contiguous areas.

TABLE 44—AVERAGE COSTS FOR THE CONTIGUOUS U.S.

Delineation	PE GPCI	Average median driver wage per hour	Annual residential real estate tax
CBA	1.04	$15.24	$3,301.60
MSA	0.93	13.95	1,943.28
Micro	0.88	13.23	1,415.56
OCBSA	0.85	12.95	1,083.05

TABLE 45—AVERAGE COSTS FOR THE NON-CONTIGUOUS U.S. (ALASKA, HAWAII)

Delineation	PE GPCI	Average median driver wage per hour	Annual residential real estate tax
CBA (Honolulu, HI)	1.17	$15.35	$1,710.00
MSA	1.11	19.12	2,863.27
Micro	1.05	15.42	1,230.27
OCBSA	1.09	21.65	1,600.30

TABLE 46—AVERAGE COSTS FOR THE NON-CONTIGUOUS U.S. (ALASKA, HAWAII, AND PUERTO RICO)

Delineation	PE GPCI	Average median driver wage per hour	Annual residential real estate tax
CBA (Honolulu, HI)	1.17	$15.35	$1,710.00
MSA	1.02	10.39	846.20
Micro	1.04	13.33	958.94
OCBSA	1.08	19.98	1,429.99

As discussed earlier, BLS separates certain CPI data based upon the following size classes: A, B/C, and D. Size A represents metropolitan areas with a population of over 1,500,000 people, size B/C represents mid-sized and small metropolitan areas (population of 50,000 to 1,500,000), and size D represents nonmetropolitan urban areas.[33] For the gas and utility CPI data in Tables 50, 51, and 52, the typical ranking was the following from highest to lowest price: (1) size class A, (2) size class B/C, and (3) size class D. This is thus similar to our other cost data summarized in Tables 43, 44, 45, and 46, in that the more populated urban areas (size class A and B/C) tended to have higher average costs than the less populated urban areas (size class D). Additionally, CPI size classes with more CBA counties (size class A and B/C) tended to have higher average costs than size classes with more non-CBA counties (size class D). Thus, we conclude based off this CPI data in Tables 47, 48, and 49, that CBAs generally have higher gas prices and residential utility prices, on average, than non-CBAs.

[33] *https://www.bls.gov/opub/mlr/1996/12/art2full.pdf.*

TABLE 47—AVERAGE PRICES FOR GASOLINE, U.S. CITY AVERAGE AND SELECTED AREAS

[Per Gallon]
Gasoline all Types

Urban area size class	National average 2016
A	$2.296
B/C	2.102
D	2.128

TABLE 48—AVERAGE RESIDENTIAL UNIT PRICES AND CONSUMPTION RANGES FOR UTILITY (PIPED) GAS AND ELECTRICITY FOR U.S. CITY AVERAGE AND SELECTED AREAS

Average Price per KWH of Electricity

Urban area size class	National average 2016
A	$0.150
B/C	0.125
D	0.117

TABLE 49—AVERAGE RESIDENTIAL UNIT PRICES AND CONSUMPTION RANGES FOR UTILITY (PIPED) GAS AND ELECTRICITY FOR U.S. CITY AVERAGE AND SELECTED AREAS

Average Price per Therm of Utility (Piped) Gas

Urban area size class	National average 2016
A	$0.949
B/C	0.894
D	0.829

5. The Average Volume of Items and Services Furnished by Suppliers in the Area Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the average volume of items and services furnished by suppliers in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We found that in virtually all cases, the average volume of items and services for suppliers when furnishing those items to the various areas is higher in CBAs than non-CBAs. As indicated in Table 50, the difference in volume is more pronounced as the size of the area in terms of population declines.

TABLE 50—ALLOWED SERVICES PER SUPPLIER IN 2015 AND 2016 FOR ITEMS SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS

Areas	Allowed services (2015)	Suppliers serving area (2015)	Allowed services per supplier (2015)	Allowed services (2016)	Suppliers serving area (2016)	Allowed services per supplier (2016)
CPAP & RADs						
CBAs	9,140,617	4,091	2,234	10,634,486	4,064	2,617
Non-CBA MSAs	4,780,160	4,977	960	5,474,533	4,918	1,113
Non-CBA Rural	4,318,843	5,519	783	4,928,348	5,372	917
Oxygen						
CBAs	6,406,412	4,667	1,373	6,265,856	4,289	1,461
Non-CBA MSAs	3,766,780	4,883	771	3,662,808	4,548	805
Non-CBA Rural	4,521,374	5,325	849	4,420,783	5,036	878
Nebulizers						
CBAs	2,088,109	7,643	273	1,769,830	6,392	277
Non-CBA MSAs	1,132,972	6,167	184	1,032,926	5,742	180
Non-CBA Rural	1,372,641	7,002	196	1,267,774	6,509	195
Standard Wheelchairs						
CBAs	1,589,682	3,428	464	1,624,569	3,419	475
Non-CBA MSAs	652,588	4,687	139	658,504	4,451	148
Non-CBA Rural	600,098	5,441	110	609,432	5,190	117
WC Accessories						
CBAs	1,339,631	2,903	461	1,388,992	2,909	477
Non-CBA MSAs	431,487	3,505	123	456,145	3,388	135
Non-CBA Rural	334,264	4,093	82	355,364	3,938	90
Hospital Beds						
CBAs	791,371	2,814	281	781,486	2,707	289
Non-CBA MSAs	314,095	3,870	81	310,312	3,647	85
Non-CBA Rural	332,047	4,460	74	331,278	4,212	79
Infusion Pumps						
CBAs	741,236	1,320	562	641,192	1,329	482
Non-CBA MSAs	305,067	1,415	216	258,168	1,388	186
Non-CBA Rural	268,204	1,589	169	224,845	1,498	150
Walkers						
CBAs	466,112	3,558	131	465,134	3,722	125
Non-CBA MSAs	255,487	5,367	48	248,570	5,138	48

TABLE 50—ALLOWED SERVICES PER SUPPLIER IN 2015 AND 2016 FOR ITEMS SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS—Continued

Areas	Allowed services (2015)	Suppliers serving area (2015)	Allowed services per supplier (2015)	Allowed services (2016)	Suppliers serving area (2016)	Allowed services per supplier (2016)
Non-CBA Rural	230,651	6,488	36	227,668	6,094	37
Commode Chairs						
CBAs	191,538	3,656	52	177,339	3,010	59
Non-CBA MSAs	69,232	3,193	22	67,323	2,838	24
Non-CBA Rural	63,932	3,845	17	61,175	3,483	18
NPWT						
CBAs	182,939	1,413	129	182,375	1,380	132
Non-CBA MSAs	86,421	1,371	63	87,326	1,347	65
Non-CBA Rural	76,583	1,565	49	79,939	1,532	52
Patient Lifts						
CBAs	161,975	2,450	66	156,168	2,223	70
Non-CBA MSAs	55,504	2,262	25	53,969	2,124	25
Non-CBA Rural	52,133	2,724	19	50,405	2,532	20
Support Surfaces						
CBAs	131,756	1,859	71	128,033	1,725	74
Non-CBA MSAs	51,675	2,186	24	50,267	2,113	24
Non-CBA Rural	47,302	2,665	18	47,402	2,519	19
TENS						
CBAs	119,135	1,164	102	53,695	1,031	52
Non-CBA MSAs	55,563	780	71	28,878	697	41
Non-CBA Rural	55,020	867	63	28,207	791	36
Seat Lifts						
CBAs	5,925	1,057	6	3,026	715	4
Non-CBA MSAs	3,774	927	4	2,652	746	4
Non-CBA Rural	6,032	1,326	5	4,439	1,151	4
Complex Wheelchairs						
CBAs	1,059	209	5	1,295	236	5
Non-CBA MSAs	581	176	3	618	199	3
Non-CBA Rural	420	140	3	544	171	3

Notes: Complex wheelchairs include Group 2 complex rehabilitative power wheelchair bases.

One factor to consider is that as a supplier's volume increases, the overall costs of furnishing those items also increases due to the need to purchase more delivery vehicles, hire additional employees, expand warehouse and office space, purchase additional office equipment, additional use of gas and other utilities, etc.

Past stakeholder input and studies suggest that delivery costs and wages affect a suppliers' overall costs more than equipment acquisition costs and volume discounts. In 2006, Morrison Informatics, Inc. conducted a study for the American Association for Homecare titled ''A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy'', which used a survey of 74 oxygen suppliers to determine which factors are more important in influencing oxygen suppliers' cost of furnishing oxygen and oxygen equipment. The study concluded that equipment acquisition only accounted for 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. This study concluded that services such as preparing and delivering equipment, driving to the home to repair and maintain equipment, training and educating patients, obtaining required medical necessity documentation, customer service, and operating and overhead costs accounted for 72 percent of overall costs. Our data indicates that delivery, wages, gasoline, utilities, office rental, and other overhead costs are lower in non-CBAs than in CBAs, and the findings of the Morrison study indicate that these costs represent a majority of the supplier's overall cost.[34]

Table 2 from the Morrison study provided a breakdown of an oxygen supplier's monthly cost per patient of $201.20 into seven components: One for equipment cost; four for labor for various tasks; one for delivery; and one for overhead, including rent and other facility costs. Table 51 represents that table from the study.

[34] Morrison Informatics, Inc., A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy (Mechanicsburg, Pa.: June 27, 2006).

TABLE 51—2006 OXYGEN SUPPLIER COST SURVEY BY MORRISON INFORMATICS, INC

Cost component	Average cost per-patient per-month
1. SYSTEM ACQUISITION [1]	$55.81
2. INTAKE AND CUSTOMER SERVICE [2]	12.66
3. PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE [3]	25.24
4. UNSCHEDULED REPAIRS AND MAINTENANCE [4]	6.10
5. PATIENT ASSESSMENT, TRAINING, EDUCATION AND MONITORING [5]	17.54
6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE [6]	42.26
7. OTHER MONTHLY OPERATING AND OVERHEAD [7]	41.59
8. TOTAL DIRECT COST BEFORE TAXES	201.20

[1] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).

[2] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.

[3] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.

[4] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.

[5] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.

[6] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.

[7] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

Table 52 combines the monthly costs from Table 2 of the Morrison study into the major components of a DME supplier's costs: Equipment cost; labor cost; delivery cost; and overhead.

TABLE 52—DOLLAR COST BREAKOUT FOR DME SUPPLIER OF OXYGEN AND OXYGEN EQUIPMENT

Monthly average cost per beneficiary	Component	Percentage of total cost (percent)
$55.81	Oxygen Equipment	28
61.54	Combined Labor Costs	30
42.26	Delivery	21
41.59	Overhead	21
201.20	Total Cost Per Month	100

The average volume of oxygen equipment furnished by suppliers in CBAs is greater than the average volume of oxygen equipment furnished by suppliers in non-CBAs, particularly rural areas, as shown previously in Table 50. But volume discounts associated with bulk purchasing of oxygen equipment, or the lack thereof, would only impact 28 percent of the suppliers' total cost per month according to the Morrison study. The Morrison study concludes that labor, delivery, and overhead costs combined account for far more of the oxygen supplier's overall cost (72 percent) than the cost of the oxygen equipment (28 percent). Even if the supplier received a 25 percent volume discount on the price of the equipment from the manufacturer, reducing its monthly cost for the equipment from $55.81 to $41.86, this savings would be more than cancelled out if the supplier's labor, delivery, and overhead costs are just 10 percent higher than the supplier in the area with lower costs and lower volume. Also, as a supplier increases their volume, the costs associated with labor, delivery, and overhead also increase proportionally. The conclusion drawn from the Morrison study is that although the average volume of oxygen and oxygen equipment furnished by suppliers in the CBAs may be higher than the average volume of oxygen and oxygen equipment furnished by suppliers in the non-CBA areas, this factor alone does not mean that the overall costs of furnishing oxygen and oxygen equipment in the CBAs is lower than the overall costs of furnishing oxygen and oxygen equipment in the non-CBAs. Our data indicates that the labor, delivery, and overhead costs of suppliers furnishing oxygen and oxygen equipment in CBAs are higher than the labor, delivery, and overhead costs of suppliers furnishing oxygen and oxygen equipment in non-CBAs, and the Morrison study concludes that these costs make up 72 percent of the oxygen supplier's overall costs.

6. Number of Suppliers Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the number of suppliers in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We examined data regarding the number of suppliers serving the various CBAs and did not find any correlation between number of suppliers and SPA or maximum winning bid amount. We are not certain how much this factor might affect costs in terms of competition for business or serving areas with a limited number of suppliers, but it does not appear to have been a factor under the competitive bidding program in terms of bids submitted in the various CBAs.

Data for number of suppliers per area and product category did not change significantly in 2016 from levels in 2015. There was at least a double digit number of suppliers serving non-CBAs in almost every MSA, micro area or other rural counties for items subject to the fee schedule reductions. The number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, while volume per supplier increased, suggesting a consolidation in

the number of locations serving the non-CBAs.

We believe that one of the most critical items subject to the fee schedule adjustments in terms of beneficiary access is oxygen and oxygen equipment. If access to oxygen and oxygen equipment is denied to a beneficiary who needs oxygen, this can have serious health implications. Oxygen and oxygen equipment is also an item that must be delivered to the beneficiary and set up and used properly in the home for safety reasons. Access to oxygen and oxygen equipment in remote areas is critical and this has been stressed by stakeholders. To determine if there were pockets of the country where access to oxygen and oxygen equipment was in jeopardy, we looked at data showing how many non-CBA counties are being served by only one oxygen supplier. This data shows that these instances are extremely rare (35 counties out of about 2,700 counties in 2016 and 2017) and that the suppliers serving these counties are all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time. Of the 35 counties, 28 have only one beneficiary using oxygen, so only one supplier could serve these counties at one time, meaning that there may be other suppliers able to serve these areas as well if there were more beneficiaries using oxygen in these areas. Also of note, 28 of these counties are from Puerto Rico (25), Alaska (2), or the Virgin Islands (1), and the suppliers for these non-contiguous areas are all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time and are continuing to serve these areas.

7. Fee Schedule Adjustment Impact Monitoring Data

Regarding adverse beneficiary health outcomes, we have been monitoring claims data from non-CBAs and it does not show any observable trends indicating an increase in adverse health outcomes such as mortality, hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, or emergency room visits in 2016, 2017, or 2018 compared to 2015 in the non-CBAs, overall. In addition, we have been monitoring data on the rate of assignment in non-CBAs and it remains high (over 99 percent) in most areas, which reflects when suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME. We are, however, soliciting comments on ways to improve our fee schedule adjustment impact monitoring data.

8. Summary of Our Findings

A brief summary of our general findings gathered in accordance with section 16008 of the Cures Act are as follows:

Highest Winning Bid

Highest winning bids from Round 2 Recompete varied widely across the CBAs and the variance does not appear to be based on any geographic factor (that is, there is no pattern of maximum bid amounts for items being higher in certain CBAs or regions of the country versus others).

Stakeholder Input

Stakeholders, most of which were suppliers, stated that the fully adjusted fee schedule amounts are not sufficient to cover supplier costs for furnishing items and services in non-CBAs. Stakeholders also stated that the number of suppliers furnishing items in these areas continues to decline, the average travel distance and cost for suppliers serving rural areas are greater than the average travel distance and cost for suppliers serving CBAs, and that the average volume of services furnished by suppliers when serving non-CBAs are lower than the average volume of services furnished by suppliers when serving CBAs. Many commenters also stated that the adjusted fee schedule amounts have caused or will cause beneficiary access issues, and that beneficiaries are going without items and that this is causing adverse health outcomes. Several commenters stated that they have reduced the size of their service area due to the level of reimbursement that they are receiving. Five commenters suggested that the adjusted fee schedule amounts be based on maximum winning bids in CBAs.

Distance

From our analysis presented in this rule, the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as FAR, OCBSAs, and super rural areas, suppliers generally must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs.

Costs

Costs, on average, are higher in CBAs than they are in the non-CBAs, for most of the cost data that we examined and presented in this proposed rule.

Volume

Overall, suppliers in CBAs have significantly more volume than suppliers in either non-CBA MSAs, micro areas, or OCBSAs, based on claims data we examined and the analysis presented in this proposed rule.

Number of Suppliers

The number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, while volume per supplier increased, suggesting a consolidation in the number of locations serving the non-CBAs. Instances of beneficiaries located in areas being served by one supplier were extremely rare, when looking at users of oxygen and oxygen equipment, and were mostly in non-contiguous areas of the country. The suppliers for these non-contiguous areas were all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time in 2016 and 2017. We also did not find any correlation between number of suppliers and SPA or maximum winning bid amount.

We are soliciting comments on these findings.

B. Current Issues

1. Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas During a Gap in the DMEPOS CBP

As indicated in section V.D.2 of section V ''Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)'' of the proposed rule, we are proposing to make changes to the DMEPOS CBP effective January 1, 2019. The proposed changes to the CBP would be effective for competitions beginning on or after January 1, 2019. The Round 2 Recompete, National Mail-Order Recompete, and Round 1 2017 contract periods of performance will end on December 31, 2018. Competitive bidding for items furnished on or after January 1, 2019 has not yet begun, and therefore, we do not expect that CBP contracts would be in place on January 1, 2019. Thus we anticipate that there would be a gap in the CBP beginning January 1, 2019. During a gap in the CBP beginning January 1, 2019, there would be no contract suppliers and payment for all items and services previously included under the CBP would be based on the lower of the supplier's charge for the item or fee schedule amounts adjusted in accordance with sections 1834(a)(1)(F) and 1842(s)(3)(B) of the Act. We are proposing specific fee schedule adjustments as a way to temporarily pay for items and services in the event of a gap in the CBP due to CMS being unable to timely recompete CBP contracts before the current

DMEPOS competitive bidding contract periods of performance end.

We are proposing three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

With regard to section 16008 of the Cures Act, we have taken the information mandated by section 16008 of the Cures Act into account as part of developing the proposed fee schedule adjustments for items and services furnished on or after January 1, 2019 through December 31, 2020, in areas that are currently non-CBAs. Section 16008 of the Cures Act first mandates that we take stakeholder input into account in making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished beginning in 2019. The information we have collected includes input from many stakeholders indicating that the fully adjusted fee schedule amounts are too low and that this is having an adverse impact on beneficiary access to items and services furnished in rural and remote areas. Industry stakeholders have stated that the fully adjusted fee schedule amounts are not sufficient to cover the supplier's costs, particularly for delivering items in rural, remote areas. We are monitoring outcomes, assignment rates, and other issues related to access of items and services such as changes in allowed services and number of suppliers. We believe it is important to continue monitoring these things before proposing a more long term fee schedule adjustment methodology using information from the CBP. If fee schedule amounts are too low, they could impact access and potentially damage the businesses that furnish DMEPOS items and services. If fee schedule amounts are too high, this increases Medicare program and beneficiary costs unnecessarily. For these reasons, we believe that we should proceed cautiously in developing fee schedule adjustment methodologies for the short term that can protect access to items, while we continue to monitor and gather data and information. We plan to address fee schedule adjustments for items furnished on or after January 1, 2021 in future rulemaking after we have continued to monitor health outcomes, assignment rates, and other information.

Section 16008 of the Cures Act mandates that we take into the account the highest amount bid by a winning supplier in a CBA. However, as previously discussed in section VI.A.2 of this proposed rule, the highest winning bids from Round 2 Recompete varied widely across the CBAs and the variance does not appear to be based on any geographic factor (that is, there is no pattern of maximum bid amounts for items being higher in certain CBAs or regions of the country versus others). Thus, we did not find any supporting evidence for the development of a payment methodology for the non-CBAs based on the highest winning bids in a CBA.

Section 16008 of the Cures Act mandates that we take into account a comparison of the average travel distance and cost associated with furnishing items and services in the area. We found that the average travel distance and cost for suppliers in non-CBAs is generally lower than the average travel distance and cost for suppliers in CBAs. However, oftentimes costs in the non-contiguous areas of the U.S., particularly in Hawaii and Alaska, were higher than costs in the contiguous areas of the U.S., for most of the cost data that we examined and presented in this rule. As noted in section VI.A.1 of this proposed rule, this was confirmed by one commenter who stated that non-contiguous areas, such as Alaska and Hawaii, face unique and greater costs due to higher shipping costs, a smaller amount of suppliers, and more logistical challenges related to delivery. Additionally, from our analysis presented in this rule, the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as FAR, OCBSAs, and super rural areas, suppliers, on average, must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs. Thus, we believe this supports a payment methodology that factors in the increased costs in non-contiguous areas, and the increased travel distance suppliers face in reaching certain rural areas.

Section 16008 of the Cures Act mandates that we take into account a comparison of the average volume of items and services furnished by suppliers in the area. We found that in virtually all cases, the average volume of items and services for suppliers when furnishing those items is higher in CBAs than non-CBAs. We believe this finding supports a payment methodology that factors in and ensures beneficiary access to items and services in non-CBAs with relatively low volume.

Finally, section 16008 of the Cures Act mandates that we take into account a comparison of the number of suppliers in the area. According to Medicare claims data, the number of supplier locations furnishing DME items and services subject to the fee schedule adjustments decreased by 22 percent from 2013 to 2016. In 2016 alone there was a little over 6 percent decline from the previous year in the number of DME supplier locations furnishing items and services subject to the fee schedule adjustments. The magnitude of this decline in DME supplier locations, from 13,535 (2015) to 12,617 (2016), indicates that the number of DME supplier locations serving these areas continues to decline. There has been a further reduction in supplier locations of 9 percent in 2017. We can attribute a certain percentage of this decline in the number of suppliers to audit, investigation, and evaluations by CMS and its contractors to enhance fraud and abuse controls to monitor suppliers. Furthermore, we have noted in section VI.A.6 of this proposed rule that instances of beneficiaries located in areas being served by one supplier were extremely rare, when looking at users of oxygen and oxygen equipment, and were mostly in non-contiguous areas of the country. The suppliers for these non-contiguous areas were all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time in 2016 and 2017. Additionally, while the number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, volume per supplier increased, suggesting a consolidation in the number of locations serving the non-CBAs. However, we are still concerned about the potential beneficiary access issues that might occur in more rural and remote areas based on this consistent decline in number of suppliers. As such, out of an abundance of caution, we believe that the consistent decline in number of suppliers supports adjusting the fee schedule amounts in a way that seeks to abate this declining trend and ensure access to items and services for beneficiaries living in rural areas and other remote areas such as Alaska,

Hawaii, Puerto Rico and other U.S. territories.

Based on the stakeholder comments, the higher costs for non-contiguous areas, the increased average travel distance in certain rural areas, the significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and the decrease in the number of non-CBA supplier locations, we believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently rural or non-contiguous non-CBAs, should be based on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). We believe that since the information from the CBP comes from bidding in non-rural areas only and in all but one case in areas located in the contiguous U.S., that full adjustments based on this information should not be applied to fee schedule amounts for items and services furnished in rural and non-contiguous areas on or after January 1, 2019. We believe that blended rates can help ensure beneficiary access to needed DME items and services in rural, remote and non-contiguous areas and better account for the differences in costs for these areas versus more densely populated areas. We believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently non-CBAs, but are not rural or non-contiguous areas, should be based on 100 percent of the adjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). Although the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, the travel distances and costs for these areas are lower than the travel distances and costs for CBAs. Because the travel distances and costs for these areas are lower than the travel distances and costs for CBAs, we believe the fully adjusted fee schedule amounts are sufficient. However, we request specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well.

In the event that the proposal outlined in section V ''Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)'', to change the method for calculating SPAs under the CBP is finalized and SPAs under future competitions are calculated based on maximum winning bids rather than the median of winning bids, this change in payments under the CBP may warrant further changes to the fee schedule adjustment methodologies under § 414.210(g)(1) through (8). We would address further changes to the fee schedule adjustment methodologies in future rulemaking.

In summary, based on stakeholder input, the higher costs for suppliers in non-contiguous areas, the longer average travel distance for suppliers furnishing items in certain rural areas, the significantly lower average volume that most non-CBA suppliers furnish, and the decrease in the number of non-CBA supplier locations, we are proposing to revise § 414.210(g)(9) and to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-CBAs by extending through December 31, 2020, the current methodology which bases the fee schedule amounts on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amount in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). We are proposing to adjust the fee schedule amounts for items and services furnished in non-rural and contiguous non-CBAs from January 1, 2019 through December 31, 2020, using the current methodologies under paragraphs (1) through (8) of § 414.210(g). We plan to continue monitoring health outcomes, assignment rates, and other information and would address fee schedule adjustments for all non-CBAs for items furnished on or after January 1, 2021, in future rulemaking.

2. Proposed Fee Schedule Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During a Gap in the DMEPOS CBP

In the event of a future gap in the CBP due to CMS being unable to timely recompete contracts under the program before the DMEPOS competitive bidding contract periods of performance end, we are proposing a fee schedule adjustment methodology that would be used to adjust the fee schedules for items and services that are currently subject to and included in competitive bidding programs. We believe that a fee schedule adjustment methodology for items and services furnished during a gap in the CBP in areas that were included in the CBP should result in rates comparable to the rates that would otherwise be established under the CBP in order to maintain the level of savings that would otherwise be achieved if the CBP was in effect. We are proposing a specific fee schedule adjustment methodology for items and services furnished within former CBAs in accordance with sections 1834(a)(1)(F) and 1834(a)(1)(G) of the Act. Specifically, we propose to add a new paragraph (10) under § 414.210(g) that would establish a methodology for adjusting fee schedule amounts paid in areas that were formerly CBAs during periods when there is a temporary lapse in the CBP. We propose to adjust the fee schedule amounts for items and services furnished in former CBAs based on the SPAs in effect in the CBA on the last day before the CBP contract periods of performance ended, increased by the projected percentage change in the CPI for all Urban Consumers (CPI–U) for the 12-month period on the date after the contract periods ended (for example, January 1, 2019). If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day after the contract period ended based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

We also propose to revise paragraph (4) under § 414.210(g), so that it does not conflict with the proposed new paragraph (10), by revising the first sentence in paragraph (4) to read: ''In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts.''

With regard to payment for non-mail order diabetic testing supplies, section 1834(a)(1)(H) of the Act mandates that payment for non-mail order diabetic testing supplies be equal to the SPAs established under the national mail order competition for diabetic testing supplies. We believe that as of January 1, 2019, we must continue payment for non-mail order diabetic supplies at the current SPA rates. These SPA rates would not be updated by inflation adjustment factors and would remain in effect until new SPA rates are established under the national mail order program. We do not believe that this statutory provision would cease to apply in situations where there is a gap in the national mail order competitions for diabetic testing supplies; and therefore, we will continue to use the SPAs for mail order diabetic testing supplies as the payment amounts for

non-mail order diabetic testing supplies in the event that there is a gap in the CBP.

We seek comments on these proposals.

C. Provisions of the Proposed Rule

We are proposing to revise the fee schedule adjustment methodology at § 414.210(g)(9) so that for items and services furnished in non-CBAs that are rural or non-contiguous areas with dates of service from January 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount. We are proposing to revise the fee schedule adjustment methodology at § 414.210(g)(9) so that for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from January 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

We also propose a methodology for adjusting the fee schedule amounts for items and services that are currently subject to competitive bidding furnished in former CBAs in the event of a lapse in the DMEPOS CBP. We propose to create a new paragraph (10) under § 414.210(g) titled ''Payment Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During Temporary Gaps in the DMEPOS CBP'' that has the following text underneath: ''During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.''

Finally, with regard to payment for non-mail order diabetic testing supplies in the event of a gap in the CBP, payment would continue at the SPA rates for mail order diabetic testing supplies as mandated by section 1834(a)(1)(H) of the Act. We would pay for non-mail order diabetic supplies at the current SPA rates until new rates are established under the national mail order program.

VII. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

A. Background

The Medicare payment rules for durable medical equipment are set forth in section 1834(a) of the Act and 42 CFR part 414, subpart D of our regulations. In general, Medicare payment for DME items and services paid on a fee schedule basis is equal to 80 percent of the lower of either the actual charge or the fee schedule amount for the item. The beneficiary coinsurance is equal to 20 percent of the lower of either the actual charge or the fee schedule amount for the item. General payment rules for DME are set forth in section 1834(a)(1) of the Act and § 414.210 of our regulations, and § 414.210 also contains paragraphs relating to maintenance and servicing of items and replacement of items. Specific payment rules for oxygen and oxygen equipment are set forth in section 1834(a)(5) of the Act and § 414.226 of our regulations. The average monthly payment to suppliers serving beneficiaries with a prescribed flow rate of greater than 4 liters per minute in 2006 was approximately $299.76. Before the enactment of the Deficit Reduction Act of 2005 (DRA), these monthly payments continued for the duration of use of the equipment, provided that Medicare Part B coverage and eligibility criteria were met. Medicare covers three types of oxygen delivery systems: (1) Stationary or portable oxygen concentrators, which concentrate oxygen in room air; (2) stationary or portable liquid oxygen systems, which use oxygen stored as a very cold liquid in cylinders and tanks; and (3) stationary or portable gaseous oxygen systems, which administer compressed oxygen directly from cylinders. There is also transfilling equipment that takes oxygen from concentrators and fills up small portable gaseous tanks. Both liquid and gaseous oxygen systems require delivery of oxygen contents. Concentrators and transfilling systems do not require delivery of oxygen contents. Medicare payment for furnishing oxygen and oxygen equipment is made on a monthly basis and the fee schedule amounts vary by State.

Effective January 1, 2006, section 5101(b) of the DRA amended section 1834(a)(5) of the Act, limiting the monthly payments for oxygen equipment to 36 months of continuous use. The limit of 36 months of payment also applies to cases where there is an oxygen flow rate of greater than 4 liters per minute. The DRA mandated that payment for the delivery of oxygen contents continue after the 36-month cap on payments for oxygen equipment. At this time, Medicare already had an established fee schedule amount or payment class for oxygen contents only for beneficiaries who owned the stationary and/or portable oxygen equipment. The monthly payment for oxygen contents for beneficiaries who purchased oxygen equipment prior to 1989 included payment for delivery of both stationary and portable contents and was approximately $156 on average in 2006. CMS implemented section 1834(a)(5) of the Act, as amended by section 5101 of the DRA, in the final rule published on November 9, 2006 in the **Federal Register**, titled ''Home Health Prospective Payment System Rule Update for Calendar Year 207 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment'', (71 FR 65884). As part of this rule, we amended § 414.226 by adding a new paragraph (c) and separate payment classes for: Oxygen generating portable equipment (OGPE) consisting of portable oxygen concentrators and transfilling equipment that met the patient's portable oxygen needs without relying on the delivery of oxygen contents; stationary oxygen contents after the 36-month rental period; and portable oxygen contents after the 36-month rental period. With the addition of the new class for OGPE, rather than receiving the standard monthly add-on payment of $31.79 for portable oxygen equipment, we established a higher amount of $51.63 per month for this new technology as opposed to furnishing portable gaseous or liquid oxygen equipment, which continued to be paid at the lower add-on payment rate of $31.79 per month.

Section 1834(a)(9)(D) of the Act provides the authority to create separate classes of oxygen and oxygen equipment. Section 1834(a)(9)(D)(ii) of the Act mandates that new, separate classes of oxygen and oxygen equipment be budget neutral; the Secretary may establish new classes for oxygen and oxygen equipment only if the establishment of such classes does not result in expenditures for any year that are less or more than the expenditures which would have been made had the

classes not been established. It is important to stress that the budget neutrality requirement in section 1834(a)(9)(D)(ii) of the Act applies regardless of whether fee schedule amounts are adjusted based on information from the DMEPOS CBP. As long as suppliers continue to get paid more for OGPE than they would otherwise be paid had the OGPE class not been established, a methodology must be employed to ensure that payments or expenditures overall are budget neutral. Since 2008, in accordance with our regulations at § 414.226(c), CMS has ensured budget neutrality each year by determining how much expenditures increased as a result of the higher paying OGPE class and reducing the monthly payment amount for stationary oxygen equipment and oxygen contents by a certain percentage to offset the increase in payments attributed to the higher amount paid for OGPE. Stakeholders have argued that the budget neutrality requirement should no longer apply in situations where the fee schedule amounts for oxygen and oxygen equipment, including the fee schedule amounts for OGPE, are adjusted based on information from the DMEPOS CBP. However, as long as the add-on payment amounts for OGPE are higher than the add-on payment amounts that would otherwise have been made for portable oxygen equipment in general, a budget neutrality offset is needed to ensure the OGPE class does not result in total expenditures for any year which are more or less than the expenditures which would have been made if the payment class had not been established.

As of January 1, 2018, the average adjusted fee schedule monthly add-on amount for OGPE was $40.08 and for portable gaseous and liquid oxygen equipment was $18.20. Either of these monthly add-on amounts is added to the average adjusted fee schedule monthly payment for stationary oxygen equipment and oxygen contents which was $72.95. We note that if the fee schedule amounts for oxygen and oxygen equipment are adjusted based on information from the DMEPOS CBP, and these adjustments result in the fees for OGPE being lower than the add-on payment amounts that would otherwise have been made for portable oxygen equipment in general, a positive rather than a negative budget neutrality offset would be needed to ensure that total expenditures for any year are not more *or less* than the expenditures which would have been made if the payment class had not been established.

B. Provisions of the Proposed Rule

1. Adding a Portable Liquid Oxygen Equipment Class

The current payment classes for oxygen and oxygen equipment are included in § 414.226(c), and include: (i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable); (ii) Portable equipment only (gaseous or liquid tanks); (iii) OGPE only; (iv) Stationary oxygen contents only; and (v) Portable oxygen contents only.

As explained earlier in the preamble, the add-on payment for OGPE is higher than the add-on payment for portable gaseous and liquid equipment. OGPE provides advantages for beneficiaries in that they do not need to rely on the delivery of oxygen contents, in contrast to beneficiaries using portable gaseous or liquid equipment. The OGPE systems are also more lightweight and therefore allow for greater ambulation for beneficiaries who cannot carry or push heavier equipment. Since adding the higher paying OGPE class, utilization of this equipment has doubled, use of portable gaseous equipment declined slightly, while use of portable liquid equipment dropped significantly and now accounts for only 2 percent of utilization of portable oxygen equipment. Although portable liquid oxygen equipment does not eliminate the need for delivery of oxygen contents, it is a more lightweight system like OGPE and promotes ambulation in beneficiaries. It is also more expensive than portable gaseous equipment to suppliers, beneficiaries, and the Medicare program. The higher payments and incentives for furnishing OGPE have in essence created a disincentive to furnish portable liquid equipment.

This proposed rule would amend our regulations at § 414.226 by using the authority at section 1834(a)(9)(D) to add separate payment classes for portable gaseous oxygen equipment only and portable liquid oxygen equipment only. Instead of having one class for portable oxygen equipment only (gaseous and liquid tanks), we propose splitting this class into two classes and increasing the add-on amount for portable liquid oxygen equipment. We propose establishing the initial add-on amounts for portable liquid oxygen equipment so that they are equal to the add-on amounts for OGPE, thus reducing the incentive to furnish OGPE over portable liquid oxygen equipment. The add-on payment amounts would be adjusted in the future based on pricing information from the DMEPOS CBP. As explained above, section 1834(a)(9)(D)(ii) of the Act mandates that these new classes be annually budget neutral; however, we do not expect this change to result in a dramatic increase in the use of portable liquid oxygen equipment, and so we do not believe the budget neutrality offset would be significant.

Suppliers furnishing oxygen and oxygen equipment in a CBA under the DMEPOS CBP must furnish portable liquid oxygen equipment in any case where a beneficiary starting a new 36-month period of continuous use for oxygen and oxygen equipment requests portable liquid oxygen equipment. This is because all of the HCPCS codes describing the different types of oxygen and oxygen equipment are items included in the respiratory equipment product category under the DMEPOS CBP and § 414.422(e)(1) requires that that a contract supplier agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. However, suppliers in non-CBAs are not required to furnish portable liquid oxygen equipment even if a beneficiary requests such equipment from a supplier, which is why we believe it is important to eliminate any disincentives for furnishing this modality that may result because of higher payments for OGPE. Thus, we believe that adding the portable liquid oxygen equipment class and adding a provision to the regulations that would ensure that the payment amount for portable liquid oxygen equipment is the same as OGPE would encourage suppliers to furnish this modality when it is requested by beneficiaries.

2. Adding a Liquid High-Flow Oxygen Contents Class

As explained above, the statute allows a 50 percent volume adjustment add-on payment to suppliers for furnishing oxygen and oxygen equipment to beneficiaries with a prescribed oxygen flow rate of more than 4 liters per minute. This provides additional payment for equipment and/or delivery of additional contents necessary to meet the needs of beneficiaries who are prescribed a large quantity of oxygen. However, this add-on payment is tied to the payment for stationary equipment, which is capped after 36 months of continuous use. Certain oxygen concentrators are capable of meeting the high flow needs of some beneficiaries and continue to be available after the 36-month cap on payments for oxygen equipment. In addition, transfilling machines can be used to fill multiple lightweight portable canisters and continue to be available after the 36-

month cap on payments for oxygen equipment.

Section 1834(a)(5)(F)(ii)(II) of the Act requires that Medicare continue to make monthly payments for the delivery and refilling of oxygen contents for the period of medical need after 36 months of continuous use. Currently, there are two classes for oxygen contents (gaseous and liquid), one for stationary oxygen contents and the other for portable oxygen contents—see § 414.226(iv) and (v). In a limited number of cases where a patient is ambulatory and is prescribed a very high flow rate of oxygen (generally greater than 6 liters per minute), a portable liquid oxygen system is the only modality that would meet their high flow, portable oxygen needs. In order to better ensure that these beneficiaries have access to the portable liquid oxygen contents necessary to meet their high flow needs, we propose to add a new separate class for ''portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.''

We propose to establish the initial fee schedule amounts for portable liquid oxygen contents for prescribed flow rates of more than 4 liters per minute by multiplying the fee schedule amounts for portable oxygen contents by 1.5 to increase the payment amount by 50 percent above the payment amount for portable oxygen contents. Like the other classes of oxygen and oxygen equipment, the fee schedule amounts for this class would be adjusted in the future based on pricing information from the DMEPOS CBP. As explained above, section 1834(a)(9)(D)(ii) of the Act mandates that this new class be annually budget neutral; however, we expect that this change will have a very minimal impact on expenditures due to the limited number of beneficiaries who require a high flow rate for oxygen and can still ambulate. Therefore, we do not believe the budget neutrality offset needed would be significant.

Table 53 compares the current classes of oxygen and oxygen equipment and the proposed classes of oxygen and oxygen equipment.

TABLE 53—CURRENT AND PROPOSED OXYGEN AND OXYGEN EQUIPMENT CLASSES

Current oxygen and oxygen equipment: 5 classes described in 414.226	Proposed oxygen and oxygen equipment: 7 classes
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).
Portable equipment only (gaseous or liquid tanks)	Portable gaseous equipment only.
	Portable liquid equipment only.
Oxygen generating portable equipment only.	Oxygen generating portable equipment only.
Stationary oxygen contents only	Stationary oxygen contents only.
Portable oxygen contents only	Portable gaseous and liquid oxygen contents only except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute.
	Portable liquid oxygen contents only for prescribed flow rates greater than four liters per minute.

3. Applying Budget Neutrality Offset to All Oxygen and Oxygen Equipment Classes

In accordance with section 1834(a)(9)(D)(ii) of the Act, the fee schedule amounts for the oxygen and oxygen equipment classes are set in a budget neutral manner for each oxygen and oxygen equipment HCPCS code. The budget neutrality offset necessary to maintain the separate class for OGPE has been exclusively applied to the stationary oxygen equipment fee schedule amount as indicated in § 414.226(c)(6). We propose to change § 414.226(c)(6) and the methodology for applying the budget neutrality offset, in addition to adding the two new oxygen and oxygen equipment classes proposed above. Rather than applying the budget neutrality offset to the payment for stationary equipment and oxygen contents only, we propose to apply the budget neutrality offset to all oxygen and oxygen equipment classes and HCPCS codes beginning January 1, 2019. To implement our proposal, a budget neutrality offset shall be applied to all HCPCS codes for oxygen equipment and oxygen contents, thereby lowering the amount of the offset applied specifically to payments for stationary oxygen. We consider applying the budget neutrality offset to all oxygen classes instead of just the stationary oxygen equipment class to be more equitable in that it would not just lower payments for suppliers of stationary oxygen equipment (some of which may never furnish OGPE), but would spread the budget neutrality offset more equitably across all classes and codes for oxygen and oxygen equipment. Table 54 is an example of the fee schedule amounts when the budget neutrality offset is applied only to the stationary oxygen equipment rate versus applying the budget neutrality offset to all oxygen classes. This particular example depicts fully adjusted fee schedule amounts, including budget neutrality adjustments, for oxygen and oxygen equipment furnished in non-rural areas in the Southeast U.S.

TABLE 54—JANUARY 1, 2018 FEES FOR CURRENT AND PROPOSED BUDGET NEUTRALITY METHODS

Current method	2018 rate	Proposed method	2018 rate
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).	$70.23	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).	$72.59
Portable equipment only (gaseous or liquid tanks)	17.29	Portable gaseous equipment only	16.04
		Portable liquid equipment only	34.73
Oxygen generating portable equipment only	37.44	Oxygen generating portable equipment only	34.73
Stationary oxygen contents only	53.32	Stationary oxygen contents only	49.46

TABLE 54—JANUARY 1, 2018 FEES FOR CURRENT AND PROPOSED BUDGET NEUTRALITY METHODS—Continued

Current method	2018 rate	Proposed method	2018 rate
Portable oxygen contents only	53.32	Portable gaseous and liquid oxygen contents only with the exception of portable liquid contents greater than four liters per minute.	49.46
		Portable liquid contents only greater than four liters per minute.	74.19

We solicit comments on these provisions.

VIII. Payment for Multi-Function Ventilators

A. Background

Section 1834(a) of the Act governs payment for DME covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule amounts for items under each of the categories are established. More importantly, the payment rules for these categories are different and in some cases mutually exclusive. Table 55 provides a summary of the payment categories, corresponding payment methodology, and statutory and regulatory sections. The main payment categories are: Inexpensive or other routinely purchased items, items requiring frequent and substantial servicing, customized items, oxygen and oxygen equipment, and other items of DME (capped rental). Some differences in the payment rules for the payment categories arise, for example, where sections 1834(a)(2), (4), (6), and (7) of the Act allow for the lump sum purchase of certain items paid under these categories, while sections 1834(a)(3) and (5) of the Act do not allow for lump sum purchase of items in those categories. Also, sections 1834(a)(2), (5), and (7) of the Act cap or limit total rental payments for items paid under these categories, whereas section 1834(a)(3) does not. With regard to rented items, section 1834(a)(7) of the Act mandates beneficiary ownership of the item after 13 months of continuous rental, whereas sections 1834(a)(2), (3), and (5) do not require transfer of ownership to the beneficiary. Finally, section 1834(a)(3) of the Act mandates that payment for covered items such as ventilators and intermittent positive pressure breathing machines be made on a monthly basis for the rental of the item, whereas ventilators that are either continuous positive airway pressure devices or intermittent assist devices with continuous positive airway pressure devices are excluded from section 1834(a)(3) of the Act. Respiratory assist devices, suction pumps (aspirators), and nebulizers fall under section 1834(a)(7) of the Act.

TABLE 55—SUMMARY OF DME EQUIPMENT PAYMENT CATEGORIES AND RULES

Payment category	Payment rules
Inexpensive or other routinely purchased items—section 1834(a)(2) of the Act	Purchase price of $150 or less, OR were routinely purchased (75 percent of the time or more) under the rent/purchase program prior to 1989, OR are speech generating devices, OR are accessories used in conjunction with nebulizers, aspirators, continuous positive airway pressure devices, respiratory assist devices, or speech generating devices. If covered, these items can be purchased new or used and can be rented; however, total payments cannot exceed the purchase new fee for the item. See 42 CFR 414.220.
Items requiring frequent and substantial servicing—section 1834(a)(3) of the Act	Items, such as ventilators, requiring frequent and substantial servicing, in order to avoid risk to the patient's health. If covered, these items can be rented as long as they are medically necessary with the supplier retaining ownership of the equipment. Payment is generally made on a monthly rental basis with no cap on the number of rental payments made as long as medically necessary. Excludes CPAP devices, respiratory assist devices, suction pumps/aspirators, and nebulizers. See 42 CFR 414.222.
Customized items—section 1834(a)(4) of the Act	Payment amounts are not calculated for a customized DME item. Customized DME is defined at 42 CFR 414.224, including customized wheelchairs. If covered, payment is made in a lump-sum amount for the purchase of the item based on the DME Medicare Administrative Contractor (MAC), Part A MAC, or Part B MAC's individual determination. See 42 CFR 414.224.
Oxygen and oxygen equipment—section 1834(a)(5) of the Act	One bundled monthly rental payment amount is made, not to exceed a 36 month cap, for all covered stationary equipment, stationary and portable contents, and all accessories used in conjunction with the oxygen equipment. An add-on payment may also be made for portable oxygen. After 36 months, payment can continue to be made on a monthly basis for oxygen contents for liquid or gaseous oxygen equipment. Payment for in-home maintenance and servicing of supplier-owned oxygen concentrators and transfilling equipment may be made every 6 months, beginning 6 months after the 36 month rental cap, for any period of medical need for the remainder of the reasonable useful lifetime of the equipment (5 years). See 42 CFR 414.226.
Other Covered Items (Other than DME)—section 1834(a)(6) of the Act	Payment under a lump sum purchase.
Other items of DME (capped rental items)—section 1834(a)(7) of the Act	Monthly rental payment amount is made not to exceed a 13 month cap at which point the beneficiary takes over ownership of the equipment. Complex rehabilitative power wheelchairs can be purchased in the first month of use. For capped rental items other than power wheelchairs, the payment amount is calculated based on 10 percent of the base year purchase price for months 1 through 3. Beginning with the fourth month, the payment amount is equal to 7.5 percent of the purchase price. For power wheelchairs, the rental payment amount is calculated based on 15 percent of the base year purchase price for months 1 through 3. Beginning with the fourth month, the fee schedule amount is equal to 6 percent of the purchase price. See 42 CFR 414.229.

The Medicare allowed amount for DMEPOS items and services paid on a fee schedule basis is equal to the lower of the supplier's actual charge or the fee schedule amount. The Medicare payment amount for a DME item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met.

B. Current Issues

Concerns have been raised by the manufacturer of a multi-function ventilator about how the separate payment categories set forth at sections 1834(a)(2) through (a)(7) of the Act would apply to a new type of ventilator, which consists of a ventilator base item classified under section 1834(a)(3) of the Act, but can also perform the function of portable oxygen equipment classified under the payment categories in sections 1834(a)(5), and the functions of a nebulizer, a suction pump, and a cough stimulator classified under paragraph (7) of section 1834(a) of the Act. For example, a new product was recently cleared by the Food and Drug Administration (FDA) as a ventilator, but can also function as a portable oxygen concentrator, nebulizer, suction pump (aspirator), and cough stimulator. The multi-function ventilator assists with serving multiple, different medical needs of beneficiaries with diagnoses such as chronic lung disease, cystic fibrosis, ALS, and muscular dystrophy. As shown in Table 56, separate DME items perform each of these functions, and the DME items that perform these functions have already been assigned separate HCPCS codes and payment amounts under the DMEPOS fee schedule. Currently, HCPCS codes E0465 and E0466 are denoted for a home ventilator item, any type, used with either an invasive interface (for example, tracheostomy tube) or non-invasive interface (for example, mask, chest shell). Portable oxygen concentrators are identified using a combination of codes E1390 plus E1392.

TABLE 56—FUNCTIONS, PAYMENT CATEGORY, AND HCPCS FOR FUNCTIONS OF A MULTI-FUNCTION VENTILATOR

HCPCS code	Function	Payment category
E0465 or E0466	Ventilator	Items requiring frequent and substantial servicing.
E1390 and E1392	Portable Oxygen Concentrator	Oxygen and oxygen equipment.
E0570	Nebulizer	Capped rental items.
E0600	Suction Pump	Capped rental items.
E0482	Cough Stimulator	Capped rental items.

We noted other concerns while considering how to categorize and pay for the multi-function ventilator. One concern is that a patient may not need all of the functions that the new multi-function ventilator performs, and there are different Medicare medical necessity coverage criteria for each of the five different functions typically performed by five different pieces of equipment. In addition, another concern we have is while section 1847(a)(2)(A) of the Act mandates the implementation of competitive bidding for covered items, the only items that comprise the multi-function ventilator that have been phased into the DMEPOS CBP at this time are portable oxygen concentrators and nebulizers. As a result, in CBAs, only contract suppliers can furnish portable oxygen concentrators or nebulizers to beneficiaries in these areas, whereas non-contract suppliers can furnish ventilators, suction pumps, and cough stimulators in these same areas. The current competitive bid product categories do not include a single item, furnished by one supplier, which performs the functions of five separate items, as the multi-function ventilator does. Upon determination that the multi-function ventilator is a covered item within the meaning of section 1834(a)(13) of the Act and its payment category, the multi-function ventilator item can be eligible for inclusion in a CBP along with other ventilator items.

To address these concerns, we reviewed the payment rules for ventilators. Section 1834(a)(1)(C) of the Act indicates that subsection (a) of section 1834 is the exclusive payment rule for these items; however, this subsection does not specifically set forth a payment category for DME items that are capable of performing the functions of other items that can be classified under the multiple, different payment categories and accompanying rules under sections 1834(a)(2) through (7) of the Act. Similarly, the regulations at 42 CFR 414.220 through 42 CFR 414.229 and program instructions currently do not address payment for the multi-function ventilator's additional functions. In addition, there is no guidance or criteria regarding how to determine which function of a new multi-function item should determine the payment category for the entire multi-function item. Furthermore, because the supplier is only furnishing one item and the patient may not need more than one of the functions/features for the duration of time the item is used by the patient, we do not believe payment should be established by summing the current separate payment amounts for each function (ventilators, oxygen concentrators, nebulizers, suction pumps, and cough stimulators) to determine the fee schedule amount for the integrated multi-function item.

We believe we should classify multi-function ventilators in the frequent and substantial servicing payment category under section 1834(a)(3) of the Act and address payment for these ventilators that can perform multiple functions. The information we gathered during our review supports our proposal to classify these items under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act. Multi-function ventilators are classified by the FDA as ventilators, instead of oxygen concentrators, nebulizers, suction pumps, or cough stimulators. We believe that section 1834(a)(1)(C) of the Act requires that DME be classified into one of the payment categories in section 1834(a)(2) through (7) of the Act. We believe that by classifying these items under section 1834(a)(3) of the Act and not under sections 1834(a)(2), (4), (5), (6), or (7) of the Act, that only the rules under section 1834(a)(3) would apply to these items. We believe this is appropriate and propose to establish fee schedule amounts for multi-function ventilators based on the current Medicare fee schedule amounts for ventilators plus an additional amount for the average cost of the various additional functions or features the equipment offers (oxygen concentration, drug nebulization, respiratory airway suction, and cough stimulation). This is

similar to how fee schedule amounts have been established for other DME items in the past, such as using the average of allowed charges for underarm crutches with shock absorbers and allowed charges for underarm crutches without shock absorbers to establish the fee schedule amounts for underarm crutches with or without shock absorbers (HCPCS code E0116), or using the average of allowed charges for walkers with a fixed height and allowed charges for walkers with an adjustable height to establish the fee schedule amounts for walkers with or without adjustable heights (HCPCS codes E0130 through E0143).

C. Provisions of the Proposed Rule

Based on our review, we are proposing to add a provision to the regulation at § 414.222(f) to establish a payment methodology for multi-function ventilators effective for dates of service on or after January 1, 2019. We believe that our proposal complies with the Medicare payment rules for DME in section 1834(a) of the Act, while recognizing and encouraging innovations in technology such as multi-function ventilators. These devices can enhance patient care and promote ambulation by eliminating the need for the patient to be tethered to several pieces of equipment. We propose that multi-function ventilators be classified under section 1834(a)(3) of the Act. Items classified under section 1834(a)(3) of the Act are paid on a continuous monthly rental basis. We are interested in receiving comments on alternatives to the approach we are taking regarding the proposed classification and payment of multi-function ventilators.

We propose to establish the monthly rental fee schedule amounts for a multi-function ventilator based on the existing monthly rental fee schedule amounts for ventilators plus payment for the average cost of the additional functions. Under this proposal, a single monthly rental fee schedule amount shall be paid to encompass the base ventilator item and its additional functional components as follows.

- The monthly rental fee schedule amount for a multi-function ventilator is equal to the monthly rental fee schedule amount for a ventilator established in § 414.222(c) and (d) plus the average of the lowest monthly cost for one additional function and the monthly cost of all additional functions, increased by the annual coverage item updates of section 1834(a)(14) of the Act.
- The monthly cost for additional functions shall be determined as follows:
  - For functions performed by items classified under § 414.222 prior to 1994 the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.
  - For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment. There are currently no multi-function ventilators on the market that perform the function for items classified under § 414.220.
  - For functions performed by items classified under § 414.226 for oxygen equipment, the monthly cost is equal to the monthly payment amount established in § 414.226(e), (f), and (g), adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.
  - For functions performed by items classified under § 414.229 for cough stimulator, the monthly cost is equal to the purchase price established in § 414.229(c), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

TABLE 57—PROPOSED PAYMENT METHOD FOR MULTI-FUNCTION VENTILATORS

[Example]

Step	Method	HCPCS codes
(1)	Base amount = ventilator monthly rental fee schedule amount	E0465 or E0466
(2)	Determine monthly rental fee schedule amount for each additional function:	
(a)	(Portable Oxygen Concentrator monthly fee schedule amount × 36 months)/60 months *	E1392 + E1390
(b)	CY 1993 Nebulizer monthly rental fee schedule amount × covered item update factor for DME to CY 2019 **.	E0570
(c)	CY 1993 Suction Pump monthly rental fee schedule amount × covered item update factor for DME to CY 2019 **.	E0600
(d)	(Cough Stimulator newly purchased fee schedule amount)/60 months *	E0482
(3)	Base amount from Step 1 + lowest cost function amount from Step 2.	
(4)	Base amount from Step 1 + all function amounts from Step 2.	
(5)	Determine Payment for Multi-function ventilator (average of step 3 and 4).	

* 5 year (60 months) reasonable useful lifetime of the equipment.
** The monthly rental amounts paid prior to 1994 included payment for the equipment and all related accessories.

Medicare coverage and payment can be available for multi-function ventilators furnished to beneficiaries who are prescribed a multi-function ventilator and meet the Medicare medical necessity coverage criteria for a ventilator and at least one of the four additional functions of the device. The fee schedule amount for the multi-function ventilator would be determined in advance for each calendar year and would not vary regardless of how many additional functions the beneficiary needs in addition to the ventilator function. We are proposing that the payment amount would be established for CY 2019 and then updated each year after 2019 using the covered item update factors mandated by section 1834(a)(14) of the Act. In the event that a patient is furnished a multi-function ventilator and only meets the Medicare medical necessity coverage criteria for a ventilator, Medicare coverage and monthly rental payments would be for the ventilator only, and payment could not be made for the other functions of the device.

We are proposing a payment method that we believe ensures an integration of the functions of the multi-function ventilator with a bundled corresponding payment amount that addresses additional functions of the items that are necessary for patient care. If a

beneficiary is furnished a multi-function ventilator, payment would be denied for any separate claims for oxygen and oxygen equipment, nebulizers and related accessories, suction pumps and related accessories, and cough stimulators and any related accessories. Thus, our proposal prevents division of the multi-function item into separate parts with separate fee schedule amounts for each function of the item, some of which have conflicting payment rules. Also, this proposed payment method lessens confusion for the supplier which could occur if the supplier were to receive varying monthly rental amounts for a multi-function item and instead permits a supplier to receive predictable monthly payments over the 60 month reasonable useful lifetime of the multi-function ventilator.

We are not proposing § 414.222(f) to apply to other DME items. Subsequent rulemaking would be necessary to address other multi-function items.

We are soliciting comments on this proposal.

IX. Including the Northern Mariana Islands in Future National Mail Order CBPs

A. Background

In our CY 2015 ESRD PPS final rule (79 FR 66223 through 66265), we said that while section 1847(a)(1)(A) of the Act provides that CBPs be established throughout the U.S., the definition of U.S. at section 210(i) of the Act does not include the Northern Mariana Islands. We therefore previously determined that the Northern Mariana Islands are not considered an area eligible for inclusion under a national mail order CBP. We finalized a proposal regarding fee schedule adjustments based on information from the national mail order program and the Northern Mariana Islands at § 414.210(g)(7) to provide that the fee schedule amounts for mail order items furnished in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts (SPAs) established under a national mail order program. We discussed how a few commenters recommended waiting for the second round of bidding for the national mail order CBP before adjusting the fee schedule amounts for mail order items furnished in the Northern Mariana Islands in order to allow more time to determine if the competitive bidding payment amounts allow for access to items and services and to acquire more pricing points over an extended period of time. The commenters further recommended increasing payment amounts for the national mail order SPA for the Northern Mariana Islands to limit any access or pricing complications. In response, we said we disagreed with these suggestions, and that the national mail order SPAs already applied to items shipped to various remote areas of the U.S. and have not resulted in any problems with access to mail order items in these areas. Therefore, we believed the SPAs could be used to adjust the mail order fee schedule amounts for the Northern Mariana Islands effective January 1, 2016.

B. Current Issues

The national mail order program for diabetic testing supplies is currently in effect in all areas of the U.S., except for the Northern Mariana Islands. Thus, the Northern Mariana Islands are currently the only non-CBA for mail order diabetic testing supplies. However, even though the Northern Mariana Islands are currently not included in the national mail order program, per § 414.210(g)(7), CMS currently pays for mail order items furnished in the Northern Mariana Islands at 100 percent of the SPAs established under the national mail order CBP. After further examining this issue, it is now our view that the Northern Mariana Islands are an area eligible for inclusion under a national mail order CBP. A Joint Resolution addressing the Northern Mariana Islands titled ''Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America'' was approved in 1976 (Pub. L. 94–241 (HJRes 549), 90 Stat 263, March 24, 1976). The Joint Resolution addresses the applicability of certain federal laws to the Northern Mariana Islands. Article V (''Applicability of Laws''), section 502(a) specifies:

''The following laws of the United States in existence as of the effective date of this Section and subsequent amendments to such laws will apply to the Northern Mariana Islands, except as otherwise noted in this Covenant: (1) Those laws which provide federal services and financial assistance programs and the federal banking laws as they apply to Guam;''

Thus, under the Joint Resolution, laws which provide federal services and financial assistance apply to the Northern Mariana Islands to the same extent as they do to Guam. CMS has recognized the Joint Resolution and taken the position that the Northern Mariana Islands fall within the definition of U.S. under Medicare in 42 CFR 411.9(a). In a proposed rule published on April 25, 2006, in the **Federal Register** titled ''Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates'', (71 FR 23996), we discussed the Joint Resolution and defined the U.S. to include the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. The Northern Mariana Islands are also included in the definition of U.S. at 42 CFR 400.200. Thus, even though the Northern Mariana Islands are not explicitly referenced in sections 1861(x) and 210(h) and (i) (which notably do reference Guam) of the Act, we believe that we can consider the Northern Mariana Islands to be part of the U.S. for the purposes of the national mail order program as well.

As such, we propose to amend § 414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order CBP, the fee schedule adjustment methodology under this paragraph would no longer apply. Under this proposed rule, the Northern Mariana Islands would be included in the CBA for all competitions under the national mail order CBP beginning on or after January 1, 2019.

We are soliciting comments on this proposal.

C. Provisions of the Proposed Rule

We propose to amend § 414.210(g)(7) to indicate that beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph would no longer apply.

We are soliciting comments on this proposal.

X. Request for Information on the Gap-Filling Process for Establishing Fees for New DMEPOS Items

In general, the statute mandates that fee schedule amounts established for DME, prosthetics and orthotics and other items be based on average payments made previously under the reasonable charge payment methodology. The criteria for determining reasonable charges are at 42 CFR 405.502. For example, the exclusive payment rule at sections 1834(a)(2), (3), (8), and (9) of the Act mandates that the fee schedule amounts for DME generally be based on average reasonable charges from 1986 and/or 1987, increased by annual covered item update factors. Since section 1834(a)(1)(C) of the Act mandates that

this be the exclusive payment rule for DME, as section 1834(h)(1)(D) of the Act does for prosthetic devices, prosthetics and orthotics, CMS is required to establish fee schedule amounts for these items based on the amounts and levels established under the reasonable charge payment periods set forth in the statute (that is, July 1, 1986 through June 30, 1987, for prosthetic devices, prosthetics and orthotics, therapeutic shoes, and most DME items).

Because there may be DMEPOS items that come on the market that were not paid for by Medicare during the reasonable charge payment periods that the statute mandates be used for establishing the fee schedule amounts for these items, we establish the fee schedule amounts for newly covered items using a ''gap-filling'' process. The gap-filling process allows Medicare to establish fee schedule amounts that align with the statutory basis for the DMEPOS fee schedule. We essentially fill the gap in the data due to the lack of historic reasonable charge payments from 1986 and 1987 by estimating what the historic reasonable charge payments would have been for the items. As described in section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100–04), CMS gap-fills by using fees for comparable equipment or prices from supplier price lists, such as mail order catalogs. The gap-filling process only applies to items not assigned existing HCPCS codes that are also not items that previously were paid for under a HCPCS code that was either deleted or revised, in other words truly new items or technology as opposed to recoded/reclassified or technologically refined items or technology. This gap-filling process can result in fee schedule amounts that greatly exceed the cost to suppliers of the new technology items (such as when inflated prices from a manufacturer were used as a proxy for supplier price lists under past gap-filling exercises) or do not cover the costs of furnishing the technology if the comparable items used for gap-filling purposes are less expensive than the new item.

We are considering if changes should be made to the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. We are soliciting comments for information on how the gap-filling process could be revised in terms of what data sources or methods could be used to estimate historic allowed charges for new technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services.

XI. DMEPOS CBP Technical Amendments

A. Background

Medicare pays for certain DMEPOS items and services furnished within competitive bidding areas based on the payment rules that are set forth in section 1847 of the Social Security Act (the Act) and 42 CFR part 414, subpart F. We propose to make two minor technical amendments to correct the existing DMEPOS CBP regulations in 42 CFR 414.422 published in the **Federal Register** on November 6, 2014, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule'' (79 FR 66120) and in § 414.423 in a final rule published in the **Federal Register** on November 29, 2010, titled ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule'' (75 FR 73169).

B. Proposed Technical Amendments

We are proposing to make minor technical amendments as follows:

- In § 414.422, we propose to correct the numbering in section (d)(4), which contains subsections (i) through (vi), but omits (ii) in the numbering sequence. This error was made when the regulation was promulgated. The proposed new numbering in section (d)(4) contains subsections (i) through (v), including (ii). The content of (d)(4) would remain the same.
- In § 414.423(i)(8), we propose removing the reference to ''42 U.S.C.'' before Title 18. This statutory citation was inadvertently included when the regulation was promulgated.

We solicit public comments on these technical amendments and request that when commenting on this section, commenters reference ''DMEPOS CBP Proposed Technical Amendments.''

XII. Burden Reduction on Comorbidities

A. Background

In the CY 2011 ESRD PPS final rule (75 FR 49094), we finalized six comorbidity categories that are eligible for a comorbidity payment adjustment, each with associated International Classification of Diseases (ICD) Clinical Modification diagnosis codes (75 FR 49100). Beginning January 1, 2011, these categories included three acute, short-term diagnostic categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) and three chronic diagnostic categories (hereditary hemolytic anemia (including sickle cell anemia), myelodysplastic syndrome, and monoclonal gammopathy).

We stated in the same rule (75 FR 49099) that we would require ESRD facilities to have documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment, utilizing specific criteria that we issued in sub-regulatory guidance, specifically the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 11, Section 60.A.5 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf*). For example, to qualify for the pericarditis comorbidity adjustment, at least two of the four following criteria must be met: Atypical chest pain; pericardial friction rub; suggestive electrocardiogram changes (for example, widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported; and new or worsening pericardial effusion. In response to such requirements, stakeholders have suggested it would require additional testing or procedures to document a comorbidity, which was not our intent. Rather, our assumption was that the patient's diagnosing physician would provide the documentation. In the CY 2011 ESRD PPS final rule (75 FR 49104), we stated that ESRD facilities will obtain diagnostic information through increased communication with their patients, their patient's nephrologists and their patient's families. If there is no documentation in the medical record, the ESRD facility would be unable to claim a comorbidity payment adjustment for that patient, but could seek payment through the outlier mechanism.

In the CY 2012 ESRD PPS final rule (76 FR 70252), we clarified that the ICD–9–CM codes eligible for the comorbidity payment adjustment are subject to the annual ICD–9–CM coding updates that occur in the hospital Inpatient Prospective Payment System final rule and are effective October 1st of each year. We explained that any updates to the ICD–9–CM codes that affect the categories of comorbidities and the diagnoses within the comorbidity categories that are eligible for a comorbidity payment adjustment would be communicated to ESRD facilities through sub-regulatory guidance. We update the list of eligible diagnosis codes on an annual basis and communicate these changes through the *CMS.gov* website.

In the CY 2016 ESRD PPS final rule (80 FR 68989 through 68990), in consideration of stakeholder concerns about the burden associated with meeting the documentation requirements for bacterial pneumonia, we finalized the elimination of the case-mix payment adjustment for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy beginning in CY 2016.

B. Proposed Documentation Requirements

In the CY 2018 ESRD PPS proposed rule (82 FR 31224), we published a request for information (RFI) related to improvements to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families and invited the public to submit their ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. The aim of the RFI was to request information that would lead to increased quality of care, lower costs, improved program integrity, and to make the health care system more effective, simple and accessible.

After a review of the comments received in response to the RFI, we have determined that the documentation requirements associated with the conditions that are eligible for the comorbidity payment adjustment should be revisited. We have heard from stakeholders that they continue to face challenges in obtaining the required documentation in order to report specific diagnosis codes and obtain the comorbidity payment adjustments. Additionally, we have determined that the ESRD PPS documentation requirements are more rigorous than the documentation requirements under other CMS payment systems that generally rely on the ICD Official Guidelines.

In order to reduce burden on ESRD facilities and provide consistent policy across Medicare payment systems, we are proposing to reduce the documentation requirements necessary for justification of the comorbidity payment adjustment. Specifically, we would no longer require that ESRD facilities obtain results from specific diagnostic tests in order to qualify for a comorbidity payment adjustment. Instead, we propose to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. This proposal does not preclude the requirement for ESRD facilities to maintain clear documentation in the beneficiary's medical record used to justify the reporting of diagnosis codes, which is also necessary for adherence to ICD Guidelines. Documentation required to meet ICD guidelines continues to be required for purposes of the adjustment.

We are soliciting comment on this proposal.

XIII. Requests for Information

This section addresses two requests for information (RFIs). Upon reviewing the RFIs, respondents are encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.[35] While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

[35] These statistics can be accessed at: *https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.*

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC ''. . . for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,[36] which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.
- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113–185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised

[36] The draft version of the trusted Exchange Framework may be accessed at: *https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete

medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548–49) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.[37] In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers of healthcare services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and in other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or by fees for provider and supplier services that the beneficiary considered to be part of an episode of care involving a hospital but were not services furnished by the hospital. We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data may not be helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including services that could be offered in more than one setting. Therefore, we are seeking public comment from all providers and suppliers, including ESRD facilities and DME suppliers, on the following:

- How should we define ''standard charges'' in various provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should ''standard charges'' be defined to mean: Average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should ''standard charges'' be defined and reported for both some measure of the average contracted rate and the chargemaster, price list or charge list? Or is the best measure of a provider's or supplier's standard charges its chargemaster, price list or charge list?
- What types of information would be most beneficial to patients, how can health care providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?
- Should providers and suppliers be required to inform patients how much their out of pocket costs for a service will be before those patients are furnished that service? How can

[37] See, for example, Medicare Provider Utilization and Payment Data, available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html.*

information on out-of-pocket costs be provided to better support patients' choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how copayment and coinsurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

- Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular service performed by that provider or supplier? If so, what changes would need to be made by providers and suppliers? What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out of pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

XIV. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day 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. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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.

B. Requirements in Regulation Text

In section II.B.1 and II.B.2.b of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2019. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data,[38] are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purposes of the data validation studies rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients.[39] The mean hourly wage of a Medical Records and Health Information Technician is $20.59 per hour. Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $41.18 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

We used these updated wage estimates along with updated facility counts and patient counts to re-estimate the total information collection burden under the ESRD QIP. We estimate the total information collection burden for the PY 2021 ESRD QIP to be $181 million, and for PY 2022, to be $202 million for a net incremental burden of $21 million.

a. Estimated Time Required To Submit Data Based on Proposed Reporting Requirements

In the CY 2016 ESRD PPS final rule (80 FR 69070), we estimated that the time required to submit measure data using CROWNWeb is 2.5 minutes per data element submitted, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files to ensure that they meet CROWNWeb's internal data format requirements.

b. Estimated Burden Associated With the Data Validation Requirements for PY 2021 and PY 2022

Section IV.B.6 of this proposed rule outlines our data validation proposals. Specifically, for the CROWNWeb validation, we are proposing to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021. Under this methodology, 300 facilities would be selected each year to submit to CMS not more than 10 records, and we would reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it would take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or

[38] *https://www.bls.gov/oes/current/oes292071.htm.*

[39] *https://www.bls.gov/oes/current/oes291141.htm.*

similar administrative staff would submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year would be approximately $30,885 (750 hours × $41.18), or an annual total of approximately $103 ($30,885/300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

Under the proposed continued study for validating data reported to the NHSN Dialysis Event Module, we are proposing to modify the sampling methodology finalized in the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767). Under the proposed modifications, we would select 150 facilities for participation in the PY 2021 validation study and 300 facilities for participation in the PY 2022 validation study. A CMS contractor would send these facilities requests for 20 patient records for each of 2 quarters of data reported in CY 2018 (for a total of 40 patient records per facility). The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it would take each facility approximately 10 hours to comply with this requirement. If 150 facilities are asked to submit records, as proposed for PY 2021, we estimate that the total combined annual burden for these facilities would be 1,500 hours (150 facilities × 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2021 would be $61,770 (1,500 hours × $41.18), or a total of approximately $412 ($61,770/150 facilities) per facility in the sample in PY 2021. If 300 facilities are asked to submit records, as proposed for PY 2022, we estimate that the total combined annual burden for these facilities would be 3,000 hours (300 facilities × 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2022 would be $123,540 (3,000 hours × $41.18), or a total of approximately $412 ($123,540/300 facilities) per facility in the sample for PY 2022. The information collection request (OMB control number 0938–1340) will be revised and sent to OMB for approval.

2. Proposed New CROWNWeb Reporting Requirements for PY 2021, PY 2022, and PY 2024

To determine the burden associated with proposed new collection of information requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In section IV.B.1.c of this proposed rule, we are proposing to modify our data collection requirements for PY 2021 by removing four reporting measures from the ESRD QIP measure set. These changes would result in a burden collection savings of approximately $12 million for PY 2021 (from an estimated $193 million in total ESRD QIP burden for PY 2021 to an estimated $181 million). Approximately $2 million of that reduction is attributable to the proposed removal of the Pain Assessment and Follow-Up reporting measure and the remaining $10 million of that reduction is attributable to the proposed removal of the Serum Phosphorus reporting measure. The total reduction in burden hours is approximately 300,000 hours (from an estimated 4.7 million burden hours for PY 2021 to an estimated 4.4 million burden hours). Approximately 40,000 hours of that reduction is attributable to the proposed removal of the Pain Assessment and Follow-Up reporting measure and the remaining 260,000 hours of that reduction is attributable to the proposed removal of the Serum Phosphorus reporting measure. The proposed removal of the other two reporting measures (Healthcare Personnel Influenza Vaccination and Anemia Management) would not affect our burden calculations because data on those measures are not reported through CROWNWeb.

In section IV.C.1 of this proposed rule, we are proposing to adopt two new measures beginning with PY 2022. We estimate that the burden associated with this new data collection requirement would be approximately $21 million, or an estimated 510,000 burden hours, and that this burden would be attributable entirely to the reporting of data on the proposed MedRec measure. Since facilities are not required to submit data to CROWNWeb for the PPPW measure, we estimate that there would be no additional burden on facilities if our proposal to adopt the PPPW measure is finalized. We estimate that the total burden increase associated with reporting data on the two new measures proposed for PY 2022 is $21 million. The information collection request under OMB control number 0938–1289 will be revised and sent to OMB.

In section IV.D.1 of this proposed rule, we are proposing to adopt one new measure beginning in PY 2024. We estimate that the burden associated with the proposed measure will be zero. Since facilities are not required to submit data to CROWNWeb for the SWR measure, there is no burden in connection with this measure in PY 2024.

3. DMEPOS Competitive Bidding Program

a. Bidding Forms A and B

Section V.D of this proposed rule outlines our proposed changes to the DMEPOS CBP. DMEPOS suppliers submit bids in order to compete to become a contract supplier to furnish competitively bid items to Medicare beneficiaries who live in a CBA. CMS publishes Request for Bids instructions to describe DMEPOS CBP requirements and to instruct bidders through the bid submission process. Bids are submitted electronically via the DMEPOS Bidding System (DBidS), which is the DMEPOS CBPs' online bidding system. The bids submitted before the close of the bid window are evaluated to determine which bidders will be offered contracts. Form A collects key business information to identify a bidder, the areas and products where the bidder chooses to bid, and pertinent information to indicate whether the bidder meets all eligibility requirements. A thorough analysis is performed of all information submitted to determine that the bidder has met all requirements, including licensure, financial, and quality standards. Form B contains key bid information including the bid amount for each item, historical experience providing each item, and specific manufacturer and model information for each item. The manufacturer and model information is utilized to populate the Medicare Supplier Directory during the contract period for bidders that are awarded a contract. CMS utilizes the combined information from Forms A and B to select winning bidders and establish single payment amounts for competitively bid items and services. The previously approved information collection request is under OMB control number 0938–1016.

All bidders must submit their information and signature(s) electronically into Forms A and B using DBidS. This system allows bidders to efficiently and consistently provide the necessary information contained on Forms A and B for CMS to review. Bidders are allowed to make changes to their bids at any time prior to the close of the bid window, at which time bidders are required to complete, approve, and certify their bids. The Competitive Bidding Implementation Contractor (CBIC) will use the appropriate technology to safely obtain and secure the bidding information that is transmitted. Assistance and technical support is available to bidders throughout the competitive bidding process. Bidders will be required to submit supporting documentation such as required financial documents, proof of a bid surety bond(s), and any network agreement(s) to the CBIC.

b. Burden Estimates (Hours and Wages) for Bidding Forms A and B

Form A is used to identify the bidder. This form includes information for all locations that would be included with the bid(s). In preparation for the next round, CMS has incorporated an update to this form that would also provide new instructions in accordance with § 414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid.

We have estimated the time to obtain a bid surety bond from a surety company (including contacting the company, filling out forms, submitting forms, filing paperwork, etc.) to be 11 minutes. Additionally, we estimate that the time to assemble and complete the new bid surety bond section of Form A to be 5 minutes. The time to submit the bid surety bond documentation is estimated to take an additional 5 minutes. Therefore, the total time to complete Form A has changed from 8 hours to 8 hours and 21 minutes. Based on the number of bidders from prior rounds of competition, we have estimated the number of respondents (bidders) to be 1,500 for the next round. Each bidder would be required to complete one Form A for each round in which it bids. We anticipate that this form would be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of $49.70, plus fringe benefits and overhead of $49.70, for a total of $99.40. This wage is based on the May 2017 Occupational Employment Statistics from the Bureau of Labor Statistics, plus fringe benefits and overhead, *https://www.bls.gov/oes/current/oes113011.htm*. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate a bid. We are seeking comments on this assumption. We estimate, based on information from previous rounds of competition, the burden for each bidder to complete Form A is 8 hours and 21 minutes, and $829.99. This estimate is based on the time it takes a bidder to develop their business strategy on which CBAs and product categories to bid; obtain their bid surety bond(s); gather the required documents; and enter and review their information.

We do not know the exact number of bidders who would bid in the next round; however, for purposes of this estimate, we would assume that the number of bidders would be roughly the same as in previous rounds of competition. We estimate there would be approximately 1,500 bidders in the next round and each bidder would complete Form A once for a total of 12,525 hours and a total cost of $1,244,985.

Bidders will use Form B to submit bids for items included in the DMEPOS CBP. This form would be completed once for each CBA and product category combination with an estimated completion time of 3 hours. Total completion time assumes the time it takes a bidder to familiarize itself on how to complete Form B, develop its bid amount and enter the applicable information into Form B. For the next round, we do not know how many bids will be submitted; however, for purposes of this estimate, we would assume the average bidder would bid in 5 CBAs in 7 product categories for an average total of 35 Form Bs. We expect the number of hours to complete Form B to decrease from previous rounds based on the removal of the expansion plan section, as well as the proposed change in bidding methodology to move to lead item pricing as described in this proposed rule. Specifically, the expansion plan section is being removed from Form B to reduce the burden for bidders as we have learned from past rounds that this information is no longer necessary. The proposed change in bidding methodology to move to lead item pricing would require bidders to only submit a single bid for an entire product category, instead of multiple bids (which can be over 100 for some product categories). We anticipate that this form would be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of $49.70, plus fringe benefits and overhead of $49.70, for a total of $99.40. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate the bid. As a result, we estimate it would require the average bidder 105 hours to complete all 35 Form Bs with a cost of $10,437. Assuming 1,500 bidders participate in the next round of the DMEPOS CBP, and each bidder completes 35 Form Bs, there would be estimated 52,500 Form Bs submitted taking an estimated 157,500 hours for a total estimated cost of $15,655,500.

The information collection request associated with the DMEPOS CBP will be revised and submitted to OMB under control number 0938–1016. These requirements are not effective until approved by OMB.

XV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XVI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order

12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2019. The proposed routine updates include the CY 2019 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to ESRD patients.

b. AKI

This rule also proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule proposes to implement requirements for the ESRD QIP, including a proposal to adopt two new measures beginning with PY 2022 and a proposal to adopt a new measure beginning with PY 2024. Failure to propose requirements for the PY 2022 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2021. In addition, proposing requirements for the PY 2022 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

d. DMEPOS

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

The proposed revisions include implementation of lead item pricing and determination of SPAs based on maximum winning bids submitted for a lead item in each product category. This rule also proposes to revise the definitions of ''bid'' and ''composite bid'' and establish a new definition for ''lead item.''

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

We are proposing to revise § 414.210(g)(9) so that for items and services furnished in rural or non-contiguous areas with dates of service from January 1, 2019 through December 31, 2020, under part 414, subpart D the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount. We are proposing to revise § 414.210(g)(9) so that for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from January 1, 2019 through December 31, 2020, under part 414, subpart D the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

We then propose to create a new paragraph (10) under § 414.210(g) titled, ''Payment Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During Temporary Gaps in the DMEPOS Competitive Bidding Program'' which has the following text underneath: ''During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.''

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This proposed rule would amend our regulations at § 414.226 by revising the payment rules for oxygen and oxygen equipment and adding a new paragraph after paragraph (c) that establishes some new oxygen and oxygen equipment payment classes effective January 1, 2019. Instead of having one class for portable oxygen equipment only (gaseous and liquid tanks), we propose establishing two classes for portable oxygen equipment: (1) One class for portable oxygen equipment (gaseous tanks) and (2) another class for portable oxygen equipment (liquid tanks.) We are also proposing to add a class for liquid oxygen contents for prescribed flow rates greater than four liters per minute and used with portable equipment. We are also proposing a new budget neutrality offset to ensure the budget neutrality of all oxygen and oxygen equipment classes added after 2006.

iv. Payment for Multi-Function Ventilators

We are proposing to add a payment rule to § 414.222(f) for multi-function ventilators that would establish payment in accordance with section 1834(a)(3) of the Act for ventilators that also perform the functions of other items of durable medical equipment subject to payment rules under paragraphs (2), (5), and (7) of section 1834(a) of the Act.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs

We propose to amend § 414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph would no longer apply.

3. Overall Impact

a. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately $220 million in payments to ESRD facilities in CY 2019, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index.

b. AKI

We are estimating approximately $37.0 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

c. ESRD QIP

For PY 2021, we have re-estimated the costs associated with information collection requirements under the Program with updated wage estimates, facility counts, and patient counts, as well as the proposed policy changes described earlier in the preamble of this proposed rule, including the proposed measure removals. We also re-estimated the payment reductions under the ESRD QIP in accordance with the proposed policy changes described earlier, including the proposed domain restructuring and reweighting. We estimate that these updates would result in an overall impact of $219 million associated with quality reporting burden and payment reductions, which includes a $12 million incremental reduction in burden in collection of information requirements and $38 million in estimated payment reductions across all facilities.

For PY 2022, we estimate that the proposed revisions to the ESRD QIP would result in an increase in overall impact to $240 million, which includes a $21 million incremental increase associated with the proposed collection of information requirements and $38 million in estimated payment reductions across all facilities.

d. DMEPOS

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

This proposed rule with comment period, which proposes to base single payment amounts on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS CBP, (which we expect could potentially be delayed until January 1, 2021) has impacts estimated by rounding to the nearer 5 million dollars and is expected to cost $10 million in Medicare benefit payments and roughly $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $0 million.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are done consistent with the rules in place as of January 1, 2018.

The impacts are expected to cost $1,050 million in Medicare benefit payments and $260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019 and ending December 31, 2020. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $45 million and $30 million, respectively.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This proposed rule establishes new payment classes for oxygen and oxygen equipment and is estimated to be budget neutral to the Medicare program and its beneficiaries.

iv. Payment for Multi-Function Ventilators

This rule proposes to establish payment rules for multi-function ventilators. The impacts are estimated by rounding to the nearer 5 million dollars and are expected to cost $15 million in Medicare benefit payments and $0 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be $0 million.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs

This change would not have a fiscal impact.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought 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 BLS (*https://www.bls.gov/oes/2017/may/naics4_621100.htm*) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.00 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this proposed rule. For each ESRD facility that reviews the rule, the estimated cost is $687.50 (6.25 hours × $110.00). Therefore, we estimate that the total cost of reviewing this

regulation rounds to $39,875. ($687.50 × 58 reviewers).

For DME suppliers, we calculate a different cost of reviewing this rule. Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review this proposed rule. For each entity that reviews this proposed rule, the estimated cost is $220.00 (2 hours × $110.00). Therefore, we estimate that the total cost of reviewing this proposed rule is $143,000 ($220.00 × 650 reviewers).

B. Detailed Economic Analysis

1. CY 2019 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2018 to estimated payments in CY 2019. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2018 and CY 2019 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of February 16, 2018, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2017 claims to 2018 and 2019 using various updates. The updates to the ESRD PPS base rate are described in section II.B.3.h of this proposed rule. Table 58 shows the impact of the estimated CY 2019 ESRD payments compared to estimated payments to ESRD facilities in CY 2018.

TABLE 58—IMPACT OF PROPOSED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2019 [1] PROPOSED RULE

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2019 changes in outlier policy (%)	Effect of 2019 changes in wage index, wage floor, and labor-related share (%)	Effect of 2019 changes in payment rate update (%)	Effect of total 2019 proposed changes (outlier, wage index and floor, labor-related share, routine updates to the payment rate) (%)
	A	B	C	D	E	F
All Facilities	7,042	44.5	0.2	0.0	1.5	1.7
Type:						
Freestanding	6,626	42.4	0.2	0.0	1.5	1.7
Hospital based	416	2.1	0.4	−0.1	1.5	1.8
Ownership Type:						
Large dialysis organization	5,355	34.4	0.2	0.0	1.5	1.7
Regional chain	871	5.7	0.3	0.1	1.5	1.9
Independent	479	2.9	0.2	0.2	1.5	2.0
Hospital based [1]	325	1.6	0.4	0.0	1.5	1.9
Unknown	12	0.0	0.1	0.3	1.5	1.9
Geographic Location:						
Rural	1,263	6.4	0.2	−0.3	1.5	1.4
Urban	5,779	38.1	0.2	0.0	1.5	1.8
Census Region:						
East North Central	1,136	6.2	0.2	−0.4	1.5	1.4
East South Central	569	3.3	0.2	−0.7	1.5	1.1
Middle Atlantic	769	5.4	0.2	0.1	1.5	1.8
Mountain	398	2.3	0.2	−0.3	1.5	1.4
New England	191	1.5	0.2	−0.3	1.5	1.4
Pacific [2]	837	6.4	0.2	1.1	1.5	2.8
Puerto Rico and Virgin Islands	51	0.3	0.1	4.5	1.5	6.2
South Atlantic	1,612	10.4	0.3	−0.3	1.5	1.5
West North Central	492	2.3	0.3	−0.3	1.5	1.5
West South Central	987	6.5	0.2	−0.1	1.5	1.7
Facility Size:						
Less than 4,000 treatments	1,689	5.9	0.2	0.0	1.5	1.8
4,000 to 9,999 treatments	2,502	11.8	0.2	−0.2	1.5	1.6
10,000 or more treatments	2,776	26.7	0.2	0.1	1.5	1.8
Unknown	75	0.2	0.4	0.3	1.5	2.2
Percentage of Pediatric Patients:						
Less than 2%	6,938	44.2	0.2	0.0	1.5	1.7
Between 2% and 19%	41	0.3	0.3	0.0	1.5	1.8
Between 20% and 49%	12	0.0	0.1	−0.4	1.5	1.3
More than 50%	51	0.0	0.1	0.2	1.5	1.8

[1] Sensipar and Parsabiv will be paid under the transitional drug add-on payment adjustment for CY 2019. In CY 2016 there was approximately $840 million in spending for Sensipar under Part D.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.3.g of this proposed rule is shown in column C. For CY 2019, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.2 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2019 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2019 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments ranging from a −0.7 percent to a 4.5 percent increase due to these proposed updates in the wage indices.

Column E shows the effect of the proposed CY 2019 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.5 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2019 of 2.2 percent and the proposed MFP adjustment of 0.7 percent.

Column F reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed wage index floor, and payment rate update. We expect that overall ESRD facilities would experience a 1.7 percent increase in estimated payments in CY 2019. The categories of types of facilities in the impact table show impacts ranging from an increase of 1.1 percent to 6.2 percent in their CY 2019 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2019, we estimate that the proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2019 would be approximately $10.6 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.2 percent in CY 2019.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.7 percent overall increase in the proposed CY 2019 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 1.7 percent in CY 2019, which translates to approximately $60 million.

e. Alternatives Considered

In section II.B.3.b of this proposed rule, we proposed changes to the wage index floor.

We considered maintaining the existing wage index floor of 0.4000 and also considered increasing the wage floor to 0.5500 and 0.5800. However, based on the analyses we have conducted, we no longer believe a wage index floor value of 0.4000 is appropriate and we are concerned about the impact a higher floor value would have on the base rate.

2. Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2018 to estimated payments in CY 2019. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2018 and CY 2019 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of February 16, 2018, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2017 claims to 2018 and 2019 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 59 shows the impact of the estimated CY 2019 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2018.

TABLE 59—IMPACT OF PROPOSED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2019 PROPOSED RULE

Facility type	Number of facilities	Number of treatments (in thousands)	Effect of 2019 changes in wage index, wage floor, and labor-related share (%)	Effect of 2019 changes in payment rate update (%)	Effect of total 2019 proposed changes (%)
	(A)	(B)	(C)	(D)	(E)
All Facilities	3,861	156.9	0.0	1.5	1.5
Type					
Freestanding	3,775	153.7	0.0	1.5	1.5
Hospital based	86	3.2	−0.1	1.5	1.4
Ownership Type					
Large dialysis organization	3,269	134.8	0.0	1.5	1.5
Regional chain	416	15.1	0.0	1.5	1.5
Independent	119	4.5	0.1	1.5	1.6
Hospital based [1]	55	2.5	0.0	1.5	1.5
Unknown	2	0.0	−0.3	1.5	1.2
Geographic Location					
Rural	691	25.7	−0.2	1.5	1.3

TABLE 59—IMPACT OF PROPOSED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2019 PROPOSED RULE—Continued

Facility type	Number of facilities	Number of treatments (in thousands)	Effect of 2019 changes in wage index, wage floor, and labor-related share (%)	Effect of 2019 changes in payment rate update (%)	Effect of total 2019 proposed changes (%)
	(A)	(B)	(C)	(D)	(E)
Urban	3,170	131.2	0.1	1.5	1.6
Census Region					
East North Central	706	29.9	−0.3	1.5	1.2
East South Central	310	10.5	−0.6	1.5	0.9
Middle Atlantic	401	16.5	0.0	1.5	1.5
Mountain	244	11.0	−0.2	1.5	1.3
New England	123	4.7	−0.4	1.5	1.1
Pacific [2]	482	27.0	1.1	1.5	2.7
Puerto Rico and Virgin Islands	2	0.0	6.0	1.5	7.6
South Atlantic	872	34.1	−0.3	1.5	1.2
West North Central	251	7.7	−0.2	1.5	1.3
West South Central	470	15.6	−0.2	1.5	1.3
Facility Size					
Less than 4,000 treatments	720	25.5	0.2	1.5	1.7
4,000 to 9,999 treatments	1,403	51.4	−0.2	1.5	1.3
10,000 or more treatments	1,716	79.1	0.1	1.5	1.6
Unknown	22	1.0	0.3	1.5	1.8
Percentage of Pediatric Patients					
Less than 2%	3,860	156.7	0.0	1.5	1.5
Between 2% and 19%	1	0.2	0.6	1.5	2.1
Between 20% and 49%	0	0.0	0.0	0.0	0.0
More than 50%	0	0.0	0.0	0.0	0.0

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the proposed CY 2019 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments of a 1.5 percent increase due to these proposed updates in the wage indices.

Column D shows the effect of the proposed CY 2019 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.5 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2019 of 2.2 percent and the MFP adjustment of 0.7 percent.

Column E reflects the overall impact, that is, the effects of the proposed wage index floor and payment rate update. We expect that overall ESRD facilities would experience a 1.5 percent increase in estimated payments in CY 2019. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 7.6 percent in their CY 2019 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and his or her physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $30.0 million would be paid to ESRD facilities in CY 2019 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The methodology that we are proposing to use to determine a facility's TPS for the PY 2022 ESRD QIP is described in section IV.C of this proposed rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP would apply to ESRD PPS payments made to the facility for services furnished in CY 2022.

For the PY 2022 ESRD QIP, we estimate that, of the 6,814 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 44.31 percent or 2,896 of the facilities would receive a payment reduction for PY 2022. The total payment reduction for all of the 2,896 facilities expected to receive a reduction is approximately $38,114,871.88. Facilities that do not receive a TPS do not receive a payment reduction.

Table 60 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

TABLE 60—ESTIMATED DISTRIBUTION OF PY 2022 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities
0.0%	3,639	55.68
0.5%	1,351	20.67
1.0%	923	14.12
1.5%	437	6.69
2.0%	185	2.83

Note: This table excludes 279 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a TPS.

To estimate whether a facility would receive a payment reduction in PY 2022, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 61.

TABLE 61—DATA USED TO ESTIMATE PY 2022 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
VAT:		
Standardized Fistula Rate	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
Long Term Catheter Rate	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
Kt/V Dialysis Adequacy Comprehensive	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
Hypercalcemia	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
STrR	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
ICH CAHPS Survey	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
SRR	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
NHSN BSI	Jan 2015–Dec 2015	Jan 2016–Dec 2016.
SHR	Jan 2015–Dec 2015	Jan 2016–Dec 2016.

For all measures except STrR and SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 and 10 patient-years at risk, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B.3.b of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2015 and 2016. Facilities were required to have a score on at least one clinical measure to receive a TPS.

To estimate the total payment reductions in PY 2022 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2016 and December 2016 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2016 through December 2016 times the estimated payment reduction percentage.

Table 62 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the performance periods used for these calculations will differ from those we propose to use for the PY 2022 ESRD QIP, the actual impact of the PY 2022 ESRD QIP may vary significantly from the values provided here.

TABLE 62—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2022

	Number of facilities	Number of treatments 2016 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	6,814	45.1	6,535	2,896	−0.40
Facility Type:					
Freestanding	6,383	42.7	6,149	2,740	−0.40
Hospital-based	431	2.4	386	156	−0.39
Ownership Type:					
Large Dialysis	5,110	34.3	4,945	2,131	−0.37
Regional Chain	871	5.8	841	341	−0.36
Independent	487	3.1	448	291	−0.69
Hospital-based (non-chain)	341	1.8	301	133	−0.44
Unknown	5	0.0	0	0	.....
Facility Size:					
Large Entities	5,981	40.1	5,786	2,472	−0.37
Small Entities [1]	828	5.0	749	424	−0.59
Unknown	5	0.0	0	0	.....
Rural Status:					
(1) Yes	1,243	6.5	1,212	380	−0.25
(2) No	5,571	38.6	5,323	2,516	−0.43
Census Region:					
Northeast	933	7.0	894	462	−0.48
Midwest	1,593	8.6	1,504	538	−0.30
South	3,048	20.4	2,929	1,463	−0.45
West	1,183	8.6	1,151	389	−0.28
U.S. Territories [2]	57	0.4	57	44	−0.99
Census Division:					
Unknown	7	0.1	7	4	−0.57
East North Central	1,109	6.4	1,037	403	−0.34
East South Central	551	3.4	534	244	−0.41
Middle Atlantic	742	5.5	710	390	−0.52
Mountain	382	2.2	370	82	−0.17
New England	191	1.5	184	72	−0.30
Pacific	801	6.3	781	307	−0.34
South Atlantic	1,572	10.5	1,498	774	−0.47
West North Central	484	2.3	467	135	−0.22
West South Central	925	6.5	897	445	−0.45
U.S. Territories [2]	50	0.4	50	40	−1.05
Facility Size (number of total treatments):					
Less than 4,000 treatments	1,127	2.0	900	301	−0.33
4,000–9,999 treatments	2,514	11.6	2,502	978	−0.35
Over 10,000 treatments	3,007	30.6	3,007	1,558	−0.45
Unknown	166	0.9	126	59	−0.50

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

b. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other outpatient facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Conditions Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

c. Effects on the Medicare Program

For PY 2022, we estimate that ESRD QIP would contribute approximately $38,114,872 in Medicare savings. For comparison, Table 63 shows the payment reductions that we estimate will be achieved by the ESRD QIP from PY 2017 through PY 2022.

TABLE 63—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEAR 2017 THROUGH 2022

Payment year	Estimated payment reductions (citation)
PY 2022	$38,114,872.

TABLE 63—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEAR 2017 THROUGH 2022—Continued

Payment year	Estimated payment reductions (citation)
PY 2021	$37,872,521.
PY 2020	$31,581,441 (81 FR 77960).
PY 2019	$15,470,309 (80 FR 69074).
PY 2018	$11,576,214 (79 FR 66257).
PY 2017	$11,954,631 (79 FR 66255).

Additionally, we estimate that the proposed removal of four reporting measures beginning with PY 2021 would reduce the information collection burden by $12 million.

d. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's

inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. To date we have been unable to examine the impact of the ESRD QIP on Medicare beneficiaries including the financial impact of the Program or the impact on the health outcomes of beneficiaries. However, in future years we are interested in examining these impacts through the addition of new measures to the Program and through the analysis of available data from our existing measures.

Additionally, in this proposed rule, we are proposing changes to the ESRD QIP to reflect the Meaningful Measures Initiative's priorities, including focusing our quality measure set on more outcome-oriented, less burdensome quality measures. We believe that the changes we are proposing, which include a reduced information collection burden of $12 million for PY 2021, will help focus the Program's measurements on the most clinically appropriate topics while ensuring that facilities are not unduly burdened by quality reporting requirements.

e. Alternatives Considered

As discussed in section IV.B.3.b of this proposed rule, we considered two alternatives for reassigning measure weights in situations where a facility does not receive a score on at least one measure but is still eligible to receive a TPS score: (1) Redistribute the weight of missing measures evenly across the remaining measures (that is, we would divide up the missing measure's weight equally across the remaining measures), and (2) redistribute the weight of missing measures proportionately across the remaining measures, based on their weight as a percentage of TPS (that is, when dividing up a missing measure's weight, we would shift a larger share of that weight to measures with a higher assigned weight; measures with a lower weight would gain a smaller portion of the missing measure's weight).

While the first policy alternative is administratively simpler to implement, we rejected this option because it would not maintain the Meaningful Measure Initiative priorities in the measure weights as effectively as the second policy alternative. In section IV.B.3 of this proposed rule, we propose an approach for reweighting the domains and measures in the ESRD QIP in PY 2021 based on the priorities identified in the Meaningful Measures Initiative. For example, we propose to assign a higher weight to measures that focus on outcomes and a lower weight to measures that focus on clinical processes. If we adopted the first policy alternative, measures that we consider a lower priority would represent a much larger share of TPS relative to measures that we consider a higher priority, in situations where a facility is missing one or more measure scores. Under the second policy alternative, when a facility is not scored on a measure, the weight of lower priority measures relative to higher priority measures would be more consistent with the weights assigned to the complete measure set. For example, if a facility was ineligible to receive a score on all the measures in both the Clinical Care Measure Domain and the Safety Measure Domain in PY 2022, the weight of the Clinical Depression and Follow-Up Measure—the lowest weight remaining in the measure set would increase from 2.5 percent of the TPS to 13.5 percent of the TPS under the first policy alternative and would increase from 2.5 percent of the TPS to 5.6 percent of the TPS under the second policy alternative. Under the same scenario, the weight of the ICH CAHPS measure—the highest weight remaining in the measure set would increase from 15 percent to 26 percent under the first policy alternative and would increase from 15 percent to 33.33 percent under the second policy alternative.

4. DMEPOS

a. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

i. Effects on Other Providers

We believe that using the maximum winning bid amount and lead item pricing to establish the SPAs and paying most contract suppliers more than they bid helps to ensure beneficiary access to DMEPOS and long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Further, lead item pricing simplifies the supplier's bidding process. We anticipate that more suppliers would compete given the simpler rules and the fact that all winning bidders would be paid at least as much as they bid. Therefore, we believe that this proposal would have a positive economic impact on bidding suppliers.

ii. Effects on the Medicare Program

This proposed rule, which proposes to base single payment amounts on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS CBP, is estimated by rounding to the nearer 5 million dollars and is expected to cost $10 million in Medicare benefit payments for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The estimate uses the current baseline which bases the SPAs on the median of winning bids. The cost of the proposal is the sum of yearly impacts. Each year's impact is the product of the projected spending on items subject to competitive bidding furnished in former CBAs for that year multiplied by the percentage increase in aggregate spending due to the change in the payment rules, in this case 0.2 percent.

In considering a future in which the current regulations remain in place (the regulatory baseline), we note that over the long run, a potential supplier would be motivated to continue bidding if its expenses are below its expectation for the median of the winning bids. As such, this long run—in which suppliers have learned the likely bidding outcomes—could result in no contracts or payments at SPA levels set too low to ensure access. In this scenario, bidders might have minimal incentive to change their bidding behavior based upon a policy switch from median to maximum winning bid to determine SPAs. After all, the baseline pricing method would award contracts to the suppliers with bids below the median at prices that at least cover their production costs. Additionally, it is possible that the behavioral response of bidders who, knowing that the SPA would be set based on the maximum winning bid, would respond by bidding more competitively in a CBP round where the payment is determined based on the maximum winning bid. The trade-off between setting the SPA using the maximum winning bid and the fact that bids are more competitive, hence lowering costs, tend to balance one another out so that the resulting SPAs would be expected to be similar to the SPAs set using median bid. This trade-off is termed Revenue Equivalency with the expected result being that bidders would respond in a manner that would mitigate the SPA determination methodology change to maximum winning bid. In other words, a relatively low impact, such as that presented in

this section, could be reasonable considering Revenue Equivalency.

As noted earlier in the preamble, median bid levels have trended lower with each successive round of competition. To the extent that factors impacting the competition are still developing, the impacts of this policy proposal may be underestimated. We request comment that would allow for refinement of the impact estimate for the final rule. We also seek comment and information on how much DMEPOS production costs change from year to year; whether the changes likely to be common across suppliers, or at least well known amongst them. We would also seek comment and information on the duration of time the bidding process requires to reach steady participation so that payment outcomes occur due to the implementation of new policies for the subsequent rounds of CBP (such as the surety bond policy that was part of the 2016 ESRD PPS final rule).

iii. Effects on Medicare Beneficiaries

This proposed rule would base single payment amounts on the maximum winning bid and implement lead item pricing in the Medicare DMEPOS CBP. The effects are estimated by rounding to the nearer 5 million dollars and to cost roughly $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $0 million. Section 503 of the Consolidated Appropriations Act of 2016 and section 5002 of the Cures Act, added section 1903(i)(27) to the Act, which prohibits federal Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement took effect January 1, 2018. Many states have started limiting payment for DME based on the Medicare rates, but the majority of the states do not currently have the ability to use rates that apply to only parts of the state, such as rates paid in CBAs or rural areas of the state.

iv. Alternatives Considered

One alternative we considered was to continue the Medicare DMEPOS CBP with no changes. This would have no economic impact on the Medicare program or its beneficiaries.

Another alternative is to implement lead item pricing based on maximum winning bids as proposed, but offer contracts based on overall demand for items and services and unadjusted supplier capacity. We believe that currently more contracts are offered under the program than are needed to meet overall demand for items and services, so this is potentially an option we could consider. For example, we currently limit a supplier's capacity to 20 percent of projected demand. We could eliminate this limit which could result in less winning contracts being offered. However, the risk is that the number of contract suppliers could be reduced too much and could lead to access problems.

b. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

In the event of a gap in the CBP beginning January 1, 2019, any enrolled supplier can furnish the items currently subject to competitive bidding in former CBAs and non-CBAs. The suppliers furnishing items in former CBAs would be paid slightly more than the current SPAs based on the median of winning bids because the proposed fee schedule adjustment methodology for items and services furnished in former CBAs would adjust the fee schedule amounts for such items and services based on the current SPAs plus a CPI–U update. We understand this proposal to be consistent with the requirements of section 1834(a)(1)(F) of the Act. The suppliers furnishing items in non-CBAs would be paid based on current fee schedule amounts.

i. Effects on the Medicare Program

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 for areas that are currently CBAs and for areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas. The impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are done consistent with the rules in place as of January 1, 2018. The impacts are expected to cost $1,050 million dollars in Medicare benefit payments for the 2-year period beginning January 1, 2019 and ending December 31, 2020.

ii. Effects on Medicare Beneficiaries

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and for areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are done consistent with the rules in place as of January 1, 2018. The impacts are expected to cost $265 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to be $45 million and $30 million, respectively.

iii. Alternatives Considered

One alternative we considered but did not propose was to establish a fee schedule adjustment methodology that uses the blended (75 unadjusted/25 adjusted) rates in all super rural and non-contiguous areas, and the blended (25 unadjusted/75 adjusted) rates in all other non-CBAs. In this alternative, the fee schedule amount for items furnished in current CBAs would be based on the current SPAs updated by the projected change in the CPI–U. This alternative is estimated by rounding to the nearer 5 million dollars and is expected to cost $30 million in Medicare benefit payments and $5 million in Medicare beneficiary cost sharing beginning

January 1, 2019. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $0 million and $0 million, respectively.

Another alternative we considered but did not propose was to maintain the current SPA determination methodology, which bases the SPA on the median of winning bids, for the CBAs and maintain the current fee schedule adjustment methodologies for the non-CBAs. This alternative is estimated by rounding to the nearer 5 million dollars and to save $1,140 million in Medicare benefit payments and $280 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $50 million and $40 million, respectively.

We request public comments on these alternatives.

c. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

i. Effects on Other Providers

Suppliers of high-flow oxygen equipment and oxygen contents would get paid more when furnishing oxygen to the high-risk beneficiaries who have been prescribed high-flow oxygen. The budget neutrality offset applied to all oxygen classes would lessen the offset applied to the stationary oxygen equipment fee schedule amount, which would be to the advantage of suppliers that furnish only stationary oxygen equipment.

ii. Effects on the Medicare Program

No fiscal impact due to the annual budget neutrality calculation.

iii. Effects on Medicare Beneficiaries

No fiscal impact due to the annual budget neutrality calculation.

iv. Alternatives Considered

One alternative we considered but did not propose was to apply the budget neutrality offset to all DME, not just to the oxygen classes as proposed. This would have no fiscal impact because it would be budget neutral.

Another alternative we considered but did not propose was to eliminate OGPE classes added in 2006 and resort back to modality neutral payments for both stationary and portable equipment. This alternative would have no fiscal impact, either.

d. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

i. Effects on Other Providers

Suppliers of high-flow oxygen equipment and oxygen contents would get paid more when furnishing oxygen to the high-risk beneficiaries who have been prescribed high-flow oxygen. The budget neutrality offset applied to all oxygen classes would lessen the offset applied to the stationary oxygen equipment fee schedule amount, which would be to the advantage of suppliers that furnish only stationary oxygen equipment.

ii. Effects on the Medicare Program

No fiscal impact due to the annual budget neutrality calculation.

iii. Effects on Medicare Beneficiaries

No fiscal impact due to the annual budget neutrality calculation.

iv. Alternatives Considered

One alternative we considered but did not propose was to apply the budget neutrality offset to all DME, not just to the oxygen classes as proposed. This would have no fiscal impact because it would be budget neutral.

Another alternative we considered but did not propose was to eliminate OGPE classes added in 2006 and resort back to modality neutral payments for both stationary and portable equipment. This alternative would have no fiscal impact, either.

e. Payment for Multi-Function Ventilators

i. Effects on Other Providers

We expect that the impact of our proposal to classify the multi-function ventilator item in the frequent and substantial servicing payment category and our proposed payment rule for determining the monthly rental fee schedule amount would overall result in a slight increase in payments to suppliers since the suppliers would continue to receive the monthly rental amount for the base ventilator item plus an additional average amount for the integrated functions. In addition, the supplier would retain ownership of the multi-function ventilator that is used and can furnish the equipment for additional separate rental periods to other beneficiaries.

ii. Effects on the Medicare Program

We expect our proposed payment rule for multi-function ventilators to be a 5-year cost of $15 million to the Medicare program as the proposed payment method would result in suppliers continuing to receive the monthly rental amount for the base ventilator item plus an additional average amount for the integrated functions.

iii. Effects on Medicare Beneficiaries

We expect the proposal would have a negligible effect on Medicare beneficiaries' copayments.

iv. Alternatives Considered

We considered two alternatives for our proposed payment rule for multi-function ventilators. One alternative payment approach is to pay a ventilator base item monthly rental amount and also pay separate, add-on monthly rental payments for each of the four additional functions of the item. This alternative is expected to have no cost to the beneficiaries or the Medicare program. Another alternative payment approach is to establish a monthly rental payment amount for a ventilator plus the monthly cost of all four additional functions. However, this payment alternative would only be allowed if the patient requires all five functions of the multi-function ventilator. This alternative is expected to have no cost to the beneficiaries or the Medicare program. Each of these alternatives did not approach the new multi-function ventilator as an integrated item that encompasses efficiencies for the suppliers, beneficiaries and the program. Also, neither of these two alternatives would address payment for multi-function ventilators in a different manner than paying for five separate items that perform the same functions. Thus, we did not elect to pursue these alternatives.

f. Including the Northern Mariana Islands in Future National Mail Order CBPs

Because this proposal would not have a fiscal impact, no detailed economic analysis is necessary.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 64, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 64—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

ESRD PPS and AKI	
Category	Transfers
Annualized Monetized Transfers From Whom to Whom	$190 million. Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments From Whom to Whom	$30 million. Beneficiaries to ESRD providers.

ESRD QIP for PY 2021	
Category	Transfers
Annualized Monetized Transfers From Whom to Whom	−$38 million. Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$181 million. The PY 2021 policy changes would result in an estimated $12 million in savings.

ESRD QIP for PY 2022	
Category	Transfers
Annualized Monetized Transfers From Whom to Whom	−$38 million. Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$202 million. The PY 2022 policy changes would result in an estimated $21 million increase.

DME Provisions: Competitive Bidding Reforms Annualization Period 2019 to 2023			
Category	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	$2 $2	2019 2019	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	$0.6 $0.6	2019 2019	7% 3%
From Whom to Whom	Federal government to Medicare providers.		

DME Provisions: Transitional Fee Adjustments Annualization Period 2019 to 2020			
Category	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	$506 $516	2019 2019	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers.		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	$128 $130	2019 2019	7% 3%
From Whom to Whom	Federal government to Medicare providers.		

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XVII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (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. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 58. Using the definitions in this ownership category, we consider 479 facilities that are independent and 325 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.9 percent increase in payments for CY 2019. An independent facility (as defined by ownership type) is also estimated to receive a 2.0 percent increase in payments for CY 2019.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $37.5 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For ESRD QIP, we estimate that of the 2,896 ESRD facilities expected to receive a payment reduction in the PY 2022 ESRD QIP, 424 are ESRD small entity facilities. We present these findings in Table 60 (''Estimated Distribution of PY 2022 ESRD QIP Payment Reductions'') and Table 61 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2022''). We estimate that the payment reductions would average approximately $13,161 per facility across the 2,896 facilities receiving a payment reduction, and $14,665 for each small entity facility. We also estimate that there are 828 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.59 percent in PY 2022.

For DMEPOS, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 85 percent of the DME industry are considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million or less in any 1 year and a small percentage are nonprofit organizations. Individuals and states are not included in the definition of a small entity. As discussed in section VI of this proposed rule, this rule would provide additional revenue to a substantial number of small rural entities, especially for certain items furnished outside of the former competitively bid areas. Therefore, the Secretary has determined that these proposed rules would have a significant economic impact on a substantial number of small entities.

Therefore, the Secretary has determined that these proposed rules would have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We solicit comment on the RFA analysis provided.

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. Any such regulatory impact 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 fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 132 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 132 rural hospital-based dialysis facilities will experience an estimated 1.6 percent increase in payments. As concerns the DME parts of the rule, our data indicates that only around 6.9 percent of small rural hospitals are organizationally linked to a DME supplier with paid claims in 2017. Thus, we do not believe the DME parts of the rule will have a significant impact on operations of a substantial number of small rural hospitals. As a result, the entire proposed rule is not estimated to have a significant impact on small rural hospitals.

Therefore, the Secretary has determined that these proposed rules would not have a significant impact on the operations of a substantial number of small rural hospitals.

XVIII. Unfunded Mandates Reform Act Analysis

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 2018, that threshold is approximately $150 million. These proposed rules do not include any mandates that would impose spending costs on state, local, or Tribal governments in the aggregate, or by the private sector, of $150 million. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

XIX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) 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 reviewed these proposed rules under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments. It is estimated that these proposals contained in section VI of this proposed rule would add $30 million dollars of additional expense to state governments because of the added cost sharing expense for Medicare and Medicaid dual eligible beneficiaries.

XX. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule is expected to be an Executive Order 13771 regulatory action due to the estimated $9 million incremental costs (see Table 64).

XXI. Congressional Review Act

These proposed rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

XXII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and is posted on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov*.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, 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 follows:

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: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 2. Section 413.177(a) is revised to read as follows:

§ 413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under § 413.171, in the case of an ESRD facility that does not earn enough points under the program described at § 413.178 to meet or exceed the minimum total performance score (as defined at § 413.178(a)(8)) established by CMS for a payment year (as defined at § 413.178(a)(10)), payments otherwise made to the facility under § 413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

(1) For every 10 points that the total performance score (as defined at § 413.178(a)(14)) earned by the ESRD facility falls below the minimum total performance score, the payments otherwise made will be reduced by 0.5 percent.

(2) [Reserved]

* * * * *

■ 3. Section 413.178 is added to read as follows:

§ 413.178 ESRD quality incentive program.

(a) *Definitions.* As used in this section:

(1) *Achievement threshold* means the 15th percentile of national ESRD facility performance on a clinical measure during the baseline period for a payment year.

(2) *Baseline period* means, with respect to a payment year, the time period used to calculate the performance standards, benchmark, improvement threshold and achievement threshold that apply to each clinical measure for that payment year.

(3) *Benchmark* means, with respect to a payment year, the 90th percentile of national ESRD facility performance on a clinical measure during the baseline period that applies to the measure for that payment year.

(4) *Clinical measure* means a measure that is scored for a payment year using the methodology described in paragraphs (d)(1)(i) through (iii) of this section.

(5) *End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)* means the program authorized under section 1881(h) of the Social Security Act.

(6) *ESRD facility* means an ESRD facility as defined in § 413.171.

(7) *Improvement threshold* means an ESRD facility's performance on a clinical measure during the baseline period that applies to the measure for a payment year.

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year, the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

(9) *Payment reduction* means the reduction, as specified by CMS, to each payment that would otherwise be made to an ESRD facility under § 413.230 for a calendar year based on the TPS earned by the ESRD facility for the corresponding payment year that is lower than the mTPS score established for that payment year.

(10) *Payment year* means the calendar year for which a payment reduction, if applicable, is applied to the payments otherwise made to an ESRD facility under § 413.230.

(11) *Performance period* means the time period during which data are

collected for the purpose of calculating an ESRD facility's performance on measures with respect to a payment year.

(12) *Performance standards* are, for a clinical measure, the performance levels used to award points to an ESRD facility based on its performance on the measure, and are, for a reporting measure, the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure.

(13) *Reporting measure* means a measure that is scored for a payment year using the methodology described in paragraph (d)(1)(iv) of this section.

(14) *Total performance score (TPS)* means the numeric score ranging from 0 to 100 awarded to each ESRD facility based on its performance under the ESRD QIP with respect to a payment year.

(b) *Applicability of the ESRD QIP.* The ESRD QIP applies to ESRD facilities as defined at § 413.171 beginning the first day of the month that is 4 months after the facility CMS Certification Number (CCN) effective date.

(c) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include, but are not limited to:

(1) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management.

(2) Measures on dialysis adequacy.

(3) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula).

(4) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based.

(d) *Performance scoring under the ESRD QIP.* (1) CMS will award points to an ESRD facility based on its performance on each clinical measure for which the ESRD facility reports the applicable minimum number of cases during the performance period for a payment year, and based on the degree to which the ESRD facility submits data and completes other actions specified by CMS for a reporting measure during the performance period for a payment year.

(i) CMS will award from 1 to 9 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark specified for that measure.

(ii) CMS will award from 0 to 9 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the improvement threshold but is less than the benchmark specified for that measure.

(iii) CMS will award 10 points to each ESRD facility whose performance on a clinical measure during the applicable performance period meets or exceeds the benchmark specified for that measure.

(iv) CMS will award from 0 to 10 points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure.

(2) CMS calculates the TPS for an ESRD facility for a payment year as follows:

(i) CMS calculates a domain score for each domain based on the total number of points the ESRD facility has earned under paragraph (d)(1) of this section for each measure in the domain and the weight that CMS has assigned to each measure.

(ii) CMS weights each domain score in accordance with the domain weight that CMS has established for the payment year.

(iii) The sum of the weighted domain scores is the ESRD facility's TPS for the payment year.

(e) *Public availability of ESRD QIP performance information.* (1) CMS will make information available to the public regarding the performance of each ESRD facility under the ESRD QIP on the Dialysis Facility Compare website, including the facility's TPS and scores on individual measures.

(2) Prior to making the information described in paragraph (e)(1) of this section available to the public, CMS will provide ESRD facilities with an opportunity to review that information, technical assistance to help them understand how their performance under the ESRD QIP was scored, and an opportunity to request and receive responses to questions that they have about the ESRD QIP.

(3) CMS will provide each ESRD facility with a performance score certificate on an annual basis that describes the TPS achieved by the facility with respect to a payment year. The performance score certificate must be posted by the ESRD facility within 15 business days of the date that CMS issues the certificate to the ESRD facility, with the content unaltered, in an area of the facility accessible to patients.

(f) *Limitation on review.* There is no administrative or judicial review of the following:

(1) The determination of the amount of the payment reduction under section 1881(h)(1) of the Act.

(2) The specification of measures under section 1881(h)(2) of the Act.

(3) The methodology developed under section 1881(h)(3) of the Act that is used to calculate TPSs and performance scores for individual measures.

(4) The establishment of the performance standards and the performance period under section 1881(h)(4) of the Act.

■ 4. Section 413.232 is amended by—

■ a. Revising paragraphs (b) introductory text and (b)(2);

■ b. Revising paragraph (c)(2);

■ c. Revising paragraph (e);

■ d. Revising paragraph (g)(2); and

■ e. Adding paragraph (g)(3).

The revisions and addition read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) *Definition of low-volume facility.* A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

* * * * *

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

(c) * * *

(2) Five (5) road miles or less from the ESRD facility in question.

* * * * *

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, for calendar year 2015, the attestation must be provided by December 31, 2014, and for calendar year 2016, the attestation must be provided by December 31, 2015.

* * * * *

(g) * * *

(2) In the case of an ESRD facility that has undergone a change of ownership wherein the ESRD facility's Medicare billing number does not change or changes due to a reclassification of facility type, the MAC relies upon the attestation and if the change results in two non-standard cost reporting periods (less than or greater than 12 consecutive months) does one of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(3) In the case of an ESRD facility that has changed their cost reporting period, the MAC relies on the attestation and does one or both of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

■ 5. Section 413.234 is amended—

■ a. In paragraph (a) by removing the definition of ''New injectable or intravenous product'' and adding the definition of ''New renal dialysis drug or biological'' in alphabetical order; and

■ b. By revising paragraphs (b) and (c).

The revisions read as follows:

§ 413.234 Drug designation process.

(a) * * *

New renal dialysis drug or biological. An injectable, intravenous, oral or other form or route of administration drug or biological that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2019 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs or biologicals are excluded until January 1, 2025.

* * * * *

(b) *Drug designation process.* New renal dialysis drugs or biologicals are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological is added to an existing ESRD PPS functional category.

(ii) The new renal dialysis drug or biological is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(2) If the new renal dialysis drug or biological is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new renal dialysis drug or biological is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new renal dialysis drug or biological is used to treat or manage;

(ii) The new renal dialysis drug or biological is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

(iii) The new renal dialysis drug or biological is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of Average Sales Price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the payment would be based on the drug manufacturer's invoice.

(1) A new renal dialysis drug or biological that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment is paid for 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

(ii) [Reserved]

(2) A new renal dialysis drug or biological that is not considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological is available, but not for less than 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

(ii) [Reserved]

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 6. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 7. Section 414.210 is amended by—

■ a. Revising paragraphs (g)(4), (7) and (9); and

■ b. Adding paragraph (g)(10).

The revisions and addition read as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated

payment adjustments would go into effect.

* * * * *

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph would no longer apply.

* * * * *

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(10) *Payment adjustments for items and services furnished in former competitive bidding areas during temporary gaps in the DMEPOS CBP.* During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

■ 8. Section 414.222 is amended by adding paragraph (f) to read as follows:

§ 414.222 Items requiring frequent and substantial servicing.

* * * * *

(f) *Multi-function ventilators*—(1) *Definition.* For the purpose of this paragraph, a multi-function ventilator is a ventilator as defined in paragraph (a)(1) of this section that also performs medically necessary functions for the patient at the same time that would otherwise be performed by one or more different items classified under § 414.220, § 414.226, or § 414.229.

(2) *Payment rule.* Effective for dates of service on or after January 1, 2019, the monthly rental fee schedule amount for a multi-function ventilator described in paragraph (f)(1) of this section is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the average of the lowest monthly cost for one additional function determined under paragraph (f)(3) of this section and the monthly cost of all additional functions determined under paragraph (f)(3), increased by the annual covered item updates of section 1834(a)(14) of the Act.

(3) *Monthly cost for additional functions.* (i) For functions performed by items classified under this section prior to 1994, the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

(ii) For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

(iii) For functions performed by items classified under § 414.226, the monthly cost is equal to the monthly payment amount established in § 414.226(e), (f), and (g) of, adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

(iv) For functions performed by items classified under § 414.229, the monthly cost is equal to the purchase price established in § 414.229 (c) of, adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

■ 9. Section 414.226 is amended—

■ a. By revising the heading of paragraph (c);

■ b. By revising paragraph (c)(6);

■ c. By revising the heading of paragraph (d);

■ d. In paragraph (d)(2) by removing the reference ''paragraph (e)(2)'' and adding in its place the reference ''paragraph (g)(2)'';

■ e. By redesignating paragraphs (e), (f) and (g) as paragraphs (g), (h), and (i); and

■ f. By adding new paragraphs (e) and (f).

The revisions and additions read as follows:

§ 414.226 Oxygen and oxygen equipment.

* * * * *

(c) *Monthly fee schedule amount for items furnished from 2007 through 2018.* * * *

* * * * *

(6) For 2008 through 2018, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) *Application of monthly fee schedule amounts for items furnished from 2007 through 2018.* * * *

* * * * *

(e) *Monthly fee schedule amount for items furnished for years after 2018.* (1) For 2019, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable gaseous equipment only.

(iii) Portable liquid equipment only.

(iv) Oxygen generating portable equipment only.

(v) Stationary oxygen contents only.

(vi) Portable oxygen contents only, except for portable liquid oxygen

contents for prescribed flow rates greater than four liters per minute.

(vii) Portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.

(2) The monthly payment rate for items described in paragraphs (e)(1)(i), (ii), (iv), (v), and (vi) of this section are determined using the applicable methodologies contained in § 414.210(g).

(3) The monthly payment rate for items described in paragraph (e)(1)(iii) of this section is determined initially based on the monthly payment rate for items described in paragraph (e)(1)(iv) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(4) The monthly payment rate for items described in paragraph (e)(1)(vii) of this section is determined initially based on 150 percent of the monthly payment rate for items described in paragraph (e)(1)(vi) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(5) Beginning in 2019, CMS makes an annual adjustment to the monthly payment rate for items described in paragraphs (e)(1)(i) through (e)(1)(vii) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(f) *Application of monthly fee schedule amounts for items furnished for years after 2018.* (1) The fee schedule amount for items described in paragraph (e)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (e)(1)(ii), (iii), and (iv) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (e)(1)(v) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (e)(1)(vi) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section; or

(ii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(5) The fee schedule amount for items described in paragraph (e)(1)(vii) of this section is paid when the beneficiary has a prescribed flow rate of more than 4 liters per minute and—

(i) Owns portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section; or

(ii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

§ 414.230 [Amended]

■ 10. Section 414.230 is amended in paragraph (h) by removing the reference ''§ 414.226(f)'' and adding in its place the reference ''§ 414.226(h)''.

■ 11. Section 414.402 is amended by revising the definitions of ''Bid'' and ''Composite bid'', and adding the definition of ''Lead item'' in alphabetical order to read as follows:

§ 414.402 Definitions.

* * * * *

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

* * * * *

Composite bid means the bid submitted by the supplier for the lead item in the product category.

* * * * *

Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

* * * * *

■ 12. Section 414.412 is amended by—

■ a. Revising paragraphs (b)(1) and (2);

■ b. Revising paragraph (c);

■ c. Revising the heading of paragraph (e); and

■ d. Revising the heading of paragraph (h).

The revisions read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(1) Composite bids, as defined in § 414.402, are submitted for lead items, as defined in § 414.402.

(2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under subpart C of this part, without the application of § 414.210(g), or subpart D of this part, without the application of § 414.105.

* * * * *

(c) *Furnishing of items.* A bid must include all costs related to furnishing all items in the product category, including all services directly related to the furnishing of the items.

(e) *Commonly-owned or controlled suppliers.* * * *

* * * * *

(h) *Requiring bid surety bonds for bidding entities.* * * *

* * * * *

■ 13. Section 414.414 is amended by revising paragraph (e) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(e) *Evaluation of bids.* CMS evaluates composite bids submitted for a lead item within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the lead item in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category;

(3) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

* * * * *

■ 14. Section 414.416 is amended by revising paragraph (b) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) *Methodology for setting payment amount.* (1) The single payment amount for a lead item furnished under a competitive bidding program is equal to the maximum or highest bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category.

(2) The single payment amount for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C or subpart D of this part.

(3) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the item to the average of the 2015 fee schedule amounts for all areas for the lead item.

§ 414.422 [Amended]

■ 15. Section 414.422 is amended by redesignating paragraphs (d)(4)(iii) through (d)(4)(vi) as paragraphs (d)(4)(ii) through (d)(4)(v).

■ 16. Section 414.423 is amended by revising paragraph (i)(8) to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

* * * * *

(i) * * *

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

* * * * *

Dated: June 26, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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