



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1691-F]

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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: Final rule.

SUMMARY: This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2019. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, it updates and rebases the ESRD market basket for CY 2019. This rule also updates requirements for the ESRD Quality Incentive Program (QIP), and makes technical amendments to correct existing regulations related to the Competitive Bidding Program (CBP) for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Finally, this rule finalizes changes to bidding and pricing methodologies under the DMEPOS competitive bidding program; 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 revises the payment methodology for mail order items furnished in the Northern Mariana Islands. This rule also includes a summary of the feedback received for the request for information related to establishing fee schedule amounts for new DMEPOS items and services.

DATES: These regulations are effective January 1, 2019, except the amendments to 42 CFR 413.234, which are effective January 1, 2020.

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.

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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:

Electronic Access

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

Addenda Are Only Available Through the Internet on the CMS Web Site

The Addenda for the annual ESRD PPS proposed and final rules will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet 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.

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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 updates and makes 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 updates 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 rule finalizes 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 finalizes revisions to 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 finalizes fee schedule adjustment methodologies 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 finalizes 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: This rule finalizes new, separate

payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and

high flow portable liquid oxygen contents. This rule also finalizes 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 finalizes payment rules for certain ventilators that are classified under section 1834(a)(3) of the Act but also perform the functions of other items of DME that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Northern Mariana Islands in Future National Mail Order CBPs: This rule finalizes changes to 42 CFR 414.210(g)(7) indicating 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 will no longer apply.

B. Summary of the Major Provisions

1. ESRD PPS

- Update to the ESRD PPS base rate for CY 2019: The final CY 2019 ESRD PPS base rate is \$235.27. This amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.3 percent), and application of the wage index budget-neutrality adjustment factor (0.999506), equaling \$235.27 ($\$232.37 \times 1.013 \times 0.999506 = \235.27).

- 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 are increasing the wage index floor, for areas with wage index values below the floor, to 0.50 and we are updating the wage index values to the latest available data.

- Update to the outlier policy: We are updating the outlier policy using the most

current data, as well as updating 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 final FDL amount for pediatric beneficiaries will increase from \$47.79 to \$57.14 and the MAP amount will decrease from \$37.31 to \$35.18, as compared to CY 2018 values. For adult beneficiaries, the final FDL amount will decrease from \$77.54 to \$65.11 and the MAP amount will decrease from \$42.41 to \$38.51. 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 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.

- Update to the drug designation process: We are updating and revising our drug designation process and expanding the transitional drug add-on payment adjustment (TDAPA) to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories. We are also changing the basis of payment for the TDAPA from pricing methodologies under section 1847A of the Act, which includes ASP+6, to ASP+0. These changes to the drug designation process and TDAPA will be effective January 1, 2020.
- Update to the low-volume payment adjustment: We are finalizing revisions to the low-volume payment adjustment regulations to allow for more flexibility with regard to attestation deadlines 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 updating the AKI payment rate for CY 2019. The final CY 2019 payment rate is \$235.27, which is the same as the base rate finalized under the ESRD PPS for CY 2019.

3. ESRD QIP

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

- We are updating 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 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 removing four measures: Healthcare Personnel Influenza Vaccination, Pain Assessment and Follow-Up, Anemia Management, and Serum Phosphorus. The removal of these measures will align the ESRD QIP measure set more closely with the priorities we have adopted as part of our Meaningful Measures Initiative.

- We are finalizing several changes to the domains 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 removing the Reporting Domain from the Program and moving each reporting measure currently in that domain (and not being removed) to another domain that is better aligned with the focus area of that measure. Additionally, we are finalizing 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, will become their own domains. As a result, the ESRD QIP will be scored using four

domains instead of three. Furthermore, we are finalizing new domain and measure weights that better align with the priority areas we have adopted as part of our Meaningful Measures Initiative.

- We are updating our policy governing when newly opened facilities must start reporting ESRD QIP data. Under our updated policy, new facilities will 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 will be required to begin reporting ESRD QIP data collected in May). The policy will provide facilities with a longer time period to learn how to properly report ESRD QIP data.

- We are increasing the number of facilities that we select for validation under the National Healthcare Safety Network (NHSN) data validation study from 35 to 150 facilities. We are also increasing 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 will improve the overall accuracy of the study.

- We are converting 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 finalizing that the 10-point deduction for failure to comply with the data request, which was first adopted for PY 2017, will become a permanent program requirement.

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

- We are adopting the Percentage of Prevalent Patients Waitlisted (PPPW) Measure and placing it in the Care Coordination Measure Domain.

- We are adopting the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure (NQF #2988) and placing it in the Safety Measure Domain.

- We are increasing the number of facilities that we select for validation under the NHSN data validation study from 150 to 300 facilities. This will further improve the overall accuracy of the study.

Finally, we are codifying 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): The rule finalizes changes to the DMEPOS CBP to implement lead item pricing based on maximum winning bid amounts, including revisions to certain definitions under 42 CFR 414.402. The definition of bid is revised 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. The definition of composite bid is revised to mean the bid submitted by the supplier for the lead item in the product category. The definition of lead item is revised 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: This rule finalizes methodologies for using the payment determined under the DMEPOS CBP to adjust fee schedule amounts for DMEPOS items and services furnished on or

after January 1, 2019. Altogether, this rule finalizes 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.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: This rule establishes new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. This rule also finalizes 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 finalizes payment rules for certain ventilators that are classified under section 1834(a)(3) of the Act but also perform the functions of other items of DME that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Northern Mariana Islands in Future National Mail Order CBPs: This rule finalizes changes to § 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 will no longer apply.

C. Summary of Costs and Benefits

In section XV of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section XV of this final 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 CY 2019 changes are projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.7 percent increase in payments compared with freestanding facilities with an estimated 1.6 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately \$210 million in CY 2019 compared to CY 2018. This reflects a \$170 million increase from the payment rate update and a \$40 million increase due to the updates to the outlier threshold amounts. As a result of the projected 1.6 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2019, which translates to approximately \$50 million.

2. Impacts of the Final Payment for Renal Dialysis Services Furnished to Individuals with AKI

The impact chart in section XV of this final 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 CY 2019 changes are projected to be a 1.3 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.2 percent increase in payments compared with freestanding facilities with an estimated 1.3 percent increase.

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

3. Impacts of the Finalized Updates to the ESRD QIP

We estimate that the overall economic impact of the ESRD QIP will be approximately \$213 million in PY 2021. The \$213 million figure for PY 2021 includes costs associated with the collection of information requirements, which we estimate will be approximately \$181 million. In PY 2022, we estimate that the overall economic impact of the ESRD QIP will be approximately \$234 million. The \$234 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate will be approximately \$202 million.

4. Impacts of the Final 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)

The rule finalizes changes to the DMEPOS CBP to implement lead item pricing based on maximum winning bid amounts. The impacts of this 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 impact on the Medicare beneficiary cost sharing is roughly \$3 million over this 5-year period. We estimate that the average per Medicare beneficiary increase in cost-sharing from median-priced SPAs to maximum-bid priced SPAs will be about \$1.50. This average increase is based on 2017 claims data which divides the aggregate \$3 million dollar cost-sharing impact by the number of

Medicare beneficiaries residing in CBAs in 2017 of about 2 million beneficiaries. 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 finalizes fee schedule adjustment methodologies for DMEPOS items and services furnished on or after January 1, 2019. Altogether, this rule finalizes 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 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 regulations at § 414.210(g). The impacts are expected to cost \$1.05 billion 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. In other words, the average per Medicare beneficiary increase in cost-sharing is about \$65.00 dollars. This average increase is based on 2017 claims data which divides the aggregate

\$260 million cost-sharing impact by the number of beneficiaries residing in CBAs and non-CBAs of about 4 million beneficiaries. 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. Section 503 of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113), and section 5002 of the 21st Century Cures Act (the Cures Act) (Pub. L. 114 – 255), 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 establishes new payment classes for oxygen and oxygen equipment and will be budget neutral to the Medicare program and its beneficiaries.

iv. Payment for Multi-Function Ventilators

This rule establishes new rules to address payment for certain ventilators that are classified under 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 \$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 beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be \$0 million.

v. Northern Mariana Islands in Future National Mail Order CBPs

This change will not have a fiscal impact because the amount paid for mail order items furnished in the Northern Mariana Islands will be the same as it would have been had the policy not changed.

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, the outlier policy, and pricing outlier drugs. For further detailed information regarding these updates, see 82 FR 50738.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2019 ESRD PPS

The proposed rule, titled “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” (83 FR 34304 through 34415), hereinafter referred to as the “CY 2019 ESRD PPS proposed rule”, was published in the **Federal Register** on July 19, 2018, with a comment period that ended on September 10, 2018. In that proposed rule, for the ESRD PPS, we proposed to make a number of annual updates for CY 2019, including updates to the ESRD PPS base rate, wage index, and outlier policy. We also proposed to revise the drug designation process and expand the TDAPA to all new renal dialysis drugs and biologicals, not just those in new ESRD PPS functional categories, and change the basis for determining the TDAPA from pricing methodologies under section 1847A of the Act (which includes ASP+6) to ASP+0. We also proposed revisions to the low-volume payment adjustment

(LVPA) regulations. We received approximately 156 public comments on our proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2019 ESRD PPS.

1. Drug Designation Process

a. Protecting Access to Medicare Act of 2014

Section 217(c) of PAMA requires the Secretary to implement 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 bundled payment under the ESRD PPS. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process, which we refer to as the drug designation process, that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral only and 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 biological products reflected in the base rate.

Under § 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 following steps occur. 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 Biological Products Reflected in the Base Rate (ESRD PPS Functional Categories)

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 provided a detailed discussion on how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011 (80 FR 69013 through 69015). In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained that in order to identify drugs and biological products 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 biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. Categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047). We grouped the injectable and intravenous drugs and biological products into functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products 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 biological products that are *not* considered used for the treatment of ESRD, categories of drugs and biological products that are *always* considered used for the treatment of ESRD, and categories of drugs and biological products 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 biological products 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 biological products 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 biological products 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 biological products 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 biological products 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 biological products 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 biological products 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 biological products 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.

In the CY 2011 ESRD PPS final rule (75 FR 49075 through 49076), Table 19 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 biological products and the amount each contributed to the base rate, except for the oral-only renal dialysis drugs where payment under the ESRD PPS was delayed. A list of the specific Part B drugs and biological products 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 final 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 biological products 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 lag¹.

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 where the ASP during first quarter of sales is unavailable, stating 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 (A) the WAC; or (B) the methodologies in effect under Medicare Part B on November 1, 2003, to determine payment amounts for drugs or biologicals. For further guidance on how Medicare Part B pays for drugs and biological products under section 1847A of the Act, see Pub. 100-04, Chapter 17, section 20 (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>).

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 biological products previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations. In the CY 2016 ESRD PPS

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>.

final rule (80 FR 69024), we adopted § 413.234(c), which requires that the TDAPA is based on pricing methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such pricing methodologies for Part B ESRD-related drugs or biological products that qualify as an outlier service (82 FR 50745).

d. Revision to the Drug Designation Process Regulation

As noted above, in prior rulemakings we addressed how new drugs and biological products are implemented under the ESRD PPS and how we have accounted for renal dialysis drugs and biological products 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 biological products in the ESRD PPS bundled payment, such new products were the primary focus of the regulation we adopted at § 413.234. We did not codify our full policy for other renal dialysis drugs, such as drugs and biological products with other forms of administration, including oral, which by law are included under the ESRD PPS (though oral-only renal dialysis drugs are excluded from the ESRD PPS bundled payment until CY 2025).

In the CY 2019 ESRD PPS proposed rule (83 FR 34311 through 34312), we proposed to revise the drug designation process regulations at § 413.234 to reflect that the process applies for all new renal dialysis drugs and biological products 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 noted in the proposed rule that for purposes of the ESRD PPS drug designation process, we use the term *form of administration* interchangeably with the term *route*

of administration. We proposed these revisions so that the regulation reflects our longstanding policy for all new renal dialysis drugs and biological products, regardless of the form or route of administration, with the exception of oral-only drugs. Specifically, we proposed to replace the definition of “new injectable or intravenous product” at § 413.234(a) with a definition for “new renal dialysis drug or biological,” which is “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,” to encompass the broader scope of the drug designation process. Under the proposed 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 Level II HCPCS 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 included the clause, “have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures.” We explained that this would be a change from the existing policy of requiring that the new product be assigned an HCPCS code. We proposed that new renal dialysis drugs or biologicals 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 happen more quickly than under our current process, wherein a lag occurs when a drug or biological product is approved but is waiting for the issuance of a code. Information

regarding the HCPCS process is available on the CMS Web site at

https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html.

We stated that 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 we noted in section II.B.1.f of the CY 2019 ESRD PPS proposed rule, even though we were 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 biological products that do not fall within an existing category), we proposed to expand the TDAPA policy based on whether the renal dialysis drug or biological product is new, that is, any renal dialysis drug or biological product newly approved on or after January 1, 2019.

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

The comments and our responses to the comments on our proposal to revise the drug designation process regulations are set forth below.

Comment: Some commenters were supportive of the proposed change to the drug designation process regulation to allow all new drugs and biological products, regardless of form or route of administration, to be eligible for the TDAPA. A drug manufacturer asserted that the proposal recognizes that new innovative products in the treatment of ESRD need not be injectables and that limiting the TDAPA to any particular category of products (for example, by mode of action, cost, or inclusion in a functional category) would be arbitrary and impair access of patients to new therapeutic agents.

Response: We appreciate the commenters' support and note that the change codifies our drug designation policy with regard to all drugs.

Comment: A national dialysis association commented that CMS should implement the proposed drug designation process consistent with the limitations in the Medicare Improvements for Patients and Providers Act of 2009 (MIPPA) on including drugs and biological products in the ESRD PPS. The association stated it is imperative to return to the statutory text of MIPPA to review precisely what categories of drugs and biological products have and have not been authorized for inclusion within the ESRD PPS. The association believes the Congress was clear that only those drugs and biological products that are furnished for the treatment of ESRD and were separately paid prior to implementation of MIPPA – specified by CMS in regulation as of January 1, 2011 – are defined as “renal dialysis services”. The association maintains that drugs and biological products approved after January 1, 2011, that are not erythropoietin stimulating agents (ESAs) or composite rate drugs, are specifically excluded from “renal dialysis services” as defined in statute and cannot be included in the ESRD PPS without a legislative change.

Response: We disagree with the commenter that section 1881(b)(14) of the Act excludes drugs and biological products approved after January 1, 2011 from being included in the ESRD PPS. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69016), we have the authority to add new renal dialysis services to the bundle under section 1881(b)(14)(B) of the Act and Congress recognized this authority under section 217(c)(2) of PAMA. First, we interpret section 1881(b)(14)(B)(iii) of the Act as requiring the inclusion of a specific category of drugs in the ESRD PPS bundled payment—that is, drugs and biological products, including those with only an oral form, furnished to individuals for the treatment of ESRD and for which separate payment was made prior to January 1, 2011. We also interpret section

1881(b)(14)(B)(iv) of the Act as specifying a different category of items that must be included in the bundle—that is, items and services, which includes drugs and biological products, not specified by sections 1881(b)(14)(B)(i), (ii), or (iii) of the Act. Second, we read the language of section 217(c)(2) of PAMA—“the Secretary of Health and Human Services . . . shall establish a process for . . . including new injectable and intravenous products into the bundled payment system”—as more than a directive to simply develop an inoperative scheme but that Congress recognized that this authority to include new drug products existed. As we discussed in the CY 2016 ESRD PPS final rule, we believe the provision required us to both define and implement a drug designation process for including new injectable and intravenous products into the bundle.

Comment: A large dialysis organization (LDO) and a national dialysis association expressed concern that the proposed regulatory text, which defines a “new drug or biological” as one “used to treat or manage a condition(s) associated with ESRD,” exceeds the statutory and regulatory definition of “renal dialysis services,” which requires that drugs and biological products included in the ESRD PPS be “for the treatment” of ESRD and be “essential for the delivery of maintenance dialysis” respectively.

Response: We did not intend to expand the definition of “new renal dialysis drug or biological” beyond use in the treatment of ESRD, and we do not believe the proposed definition in § 413.234 does that. With regard to limiting the definition to those drugs and biological products that are essential to the delivery of maintenance dialysis, we believe all drugs that fit into our existing ESRD PPS functional categories are essential to the delivery of maintenance dialysis because they are necessary to treat or manage conditions associated with the beneficiary’s ESRD, and thus, help the beneficiary to remain sufficiently healthy to continue receiving maintenance dialysis.

Comment: A drug manufacturer stated that CMS should avoid uncertainty about whether the definition of “new renal dialysis drug or biological” applies to oral-only drugs. The commenter recommended revising the last sentence in the proposed definition of “new renal dialysis drug or biological” in § 413.234(a) from “Oral-only drugs and biologicals are excluded until January 1, 2025,” to “Oral-only drugs and biologicals will be included after December 31, 2024.” The commenter believed this would clarify that oral-only drugs qualify for the TDAPA payment for new drugs and biological products once the statutory carve-out for oral-only drugs ends.

Response: We believe the proposed definition of “new renal dialysis drug or biological” with regard to oral-only drugs is sufficiently clear regarding the timing of when oral-only drugs will be included in the ESRD PPS bundled payment. As specified in § 413.174(f)(6), oral-only renal dialysis drugs and biologicals will be included in the ESRD PPS bundled payment amount effective January 1, 2025. That is, oral-only drugs will be treated in the same manner as other renal dialysis drugs and biological products with other routes of administration, beginning January 1, 2025. However, we are making a technical change to revise the definition from “Oral-only drugs and biologicals are excluded until January 1, 2025,” to “Oral-only drugs are excluded until January 1, 2025,” because “oral-only drugs” is a defined term in § 413.234(a) that includes biological products.

Comment: A drug manufacturer recommended that CMS revise the criterion pertaining to the date of FDA approval from January 1, 2019 to January 1, 2018, to include the most current drug therapy innovations. The commenter explained that the proposals in the CY 2019 ESRD PPS proposed rule are significant changes from last year’s rule, which was the first application of the new drug designation process. Specifically, the commenter recommended CMS define new

renal dialysis drugs or biological products as drugs or biological products that were FDA-approved on or after January 1, 2018, that are commercialized, and designated by CMS as a renal dialysis service under § 413.171. The commenter explained that its recommended policy should not affect the past application of the payment, that is, it would be prospective from January 1, 2019 onward.

Response: We believe that when the commenter refers to the proposals in the CY 2019 proposed rule as being “significant changes from last year’s rule, which was the first application of the new drug designation process,” the commenter is confusing the original effective date for the TDAPA policy (January 1, 2016) with the date when the TDAPA was first implemented with respect to certain drugs (January 1, 2018). Specifically, we believe the commenter is referring to the January 1, 2018 date when ESRD facilities began to receive the TDAPA for calcimimetics, the first drugs to meet the criteria for the TDAPA. We finalized the policies for the drug designation process, including the applicability of TDAPA, in our regulations at § 413.234 in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027). Furthermore, the proposed CY 2019 revisions to the drug designation process regulations are an expansion of those finalized in the CY 2016 ESRD PPS final rule since all new drugs would be eligible for the TDAPA, whereas before only new drugs that did not fall within an existing ESRD PPS functional category were eligible for the payment adjustment. We disagree with the commenter that the policy should be effective January 1, 2018 because with prospective rulemaking under the ESRD PPS, we generally do not finalize retroactive policies. That is, we generally use historical data, behaviors, and trends to make data-driven changes for the future year(s). In addition, as we discussed in the CY 2019 ESRD PPS proposed rule, the purpose of the TDAPA eligibility expansion is to give the new renal dialysis drugs and biological products a foothold in the market

so that when the TDAPA timeframe is complete, they are able to compete with the existing drugs and biologicals under the outlier policy, if applicable. Making the policy retroactive to drugs that are FDA-approved as of January 1, 2018 would create an uneven playing field because those drugs would have a 2-year head start for uptake compared to drugs that are FDA-approved and commercialized as of January 1, 2020 (which, as discussed below, is the effective date we are finalizing for the TDAPA expansion). We believe that drugs with FDA approval and commercialization in 2018 would already have achieved that foothold if the dialysis centers saw the advantage of utilizing these new drugs. Therefore, we do not believe it would be appropriate to finalize this policy retroactively to apply to drugs or biological products FDA-approved on or after January 1, 2018.

Comment: A drug manufacturer requested clarification on the term “new biological” and questioned if this term would also include biosimilars as defined in § 414.902, “a biosimilar biological product approved under an abbreviated application for a license of a biological product.”

Response: The proposed definition of “new renal dialysis drug or biological” specified that the drug or biological is required to 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.” Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act) include applications for all new drugs and biological products, including generic drugs approved under 505(j) of the FD&C Act and biological products approved under section 351(k) of the PHS Act, the abbreviated pathway created by the Biologics Price Competition and Innovation Act of 2009.

We are finalizing a revision at § 413.234(a) to change “new renal dialysis drug or biological” to “new renal dialysis drug or biological product,” to be consistent with FDA nomenclature. For the same reason, we are changing the references to “biological” within the proposed definition to refer to “biological product” instead.

Comment: We received several comments regarding the proposed clause, “have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures.” One drug manufacturer expressed support for the proposed definition and agreed with CMS’s rationale that referring to submission of a HCPCS code application versus assignment of a code allows for quicker application of the TDAPA.

MedPAC recommended that the proposed revisions to the drug designation process, discussed in section II.B.1 of this final rule, should only apply to new renal dialysis drugs and biological products that have been assigned a HCPCS code. MedPAC explained that applying the proposed policy to new drugs that have not been assigned a HCPCS code could undermine the HCPCS process. MedPAC further explained that the proposed policy could result in overpayments by beneficiaries and taxpayers for a drug that the CMS HCPCS workgroup concludes fits into an existing HCPCS code. MedPAC stated that if CMS proceeds with this proposal, the agency should establish a policy for addressing situations in which an application does not lead directly to the assignment of a new HCPCS code.

Several commenters pointed out that under the proposal, submission of a Level II HCPCS application could initiate the data collection period for drugs or biological products for TDAPA. As such, the commenters asserted data collection could begin prior to a drug or biological product’s launch, effectively shortening the period and decreasing available data. The commenters requested that CMS confirm that a Level II HCPCS application would trigger

eligibility for the TDAPA, but that the data collection period commences when the drug or biological product receives the HCPCS code. The commenters further requested that concurrent with the code being issued, CMS release detailed clinical and billing guidance regarding the drug or biological product.

Response: We understand from these comments that the main concern with the proposed clause, “have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures” is how it relates to the duration of the TDAPA for the particular drug or biological product. We note that the definition of a “new renal dialysis drug or biological product” includes other requirements that must be met in addition to the submission of a HCPCS application, and we therefore believe beginning our review of the drug when the HCPCS application is received does not undermine the HCPCS process. The other requirements include that the drug must have FDA approval, be commercially available, and be designated by CMS as a renal dialysis service. Also, as discussed on our website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html>, stakeholders must notify the Division of Chronic Care Management in our Center for Medicare of the interest for eligibility for the TDAPA and provide the information requested. We plan to work collaboratively with the CMS HCPCS workgroup when determining whether a drug or biological product is a renal dialysis service and how it should be coded. The materials submitted with the HCPCS application also assist in determining if the new drug or biological product fits into an existing ESRD PPS functional category or if it represents a new functional category. The submission of a Level II HCPCS code application is simply one criterion for the drug or biological product to be eligible for the TDAPA. Once the information is received and reviewed, we will issue a change request with billing guidance that will provide

notice that the drug is eligible for TDAPA as of a certain date and guidance on how to report the new drug or biological product on the ESRD claim for purposes of TDAPA. The effective date of this change request will initiate the TDAPA payment period and, for drugs that do not fall within a functional category, the data collection period. Information regarding the duration of the TDAPA period is discussed in section II.B.1.g of this final rule. CMS will issue any applicable clinical guidance when necessary.

With regard to the suggestion that the definition should only recognize new renal dialysis drugs and biological products that have been assigned a HCPCS code, we note that in section II.B.1.g of this final rule, we are finalizing a policy that the TDAPA will apply for all new renal dialysis drugs and biological products regardless of whether they fall within a functional category. That is, we are finalizing a policy where eligibility for TDAPA is based upon the definition of a new renal dialysis drug or biological product rather than a new HCPCS code. We therefore believe that our approach should shift away from requiring the assignment of an HCPCS code to the submission of an HCPCS application. The final policy does not depend on assignment of a new HCPCS code. We do not believe this would lead to overpayments because the final TDAPA policy recognizes all new renal dialysis drugs and biological products, and we do not agree that using the HCPCS process in this way undermines or weakens the process. As noted previously, we will issue further billing guidance for drugs and biological products that are eligible for the TDAPA, including those that are not assigned a unique HCPCS code.

We believe it is appropriate for the definition to require the submission of a HCPCS application since we will use that information to evaluate whether the new renal dialysis drug or biological product falls into an existing ESRD PPS functional category or a new functional category. We will evaluate whether any additional operational changes are needed in light of the

new TDAPA eligibility criteria we are finalizing, and issue guidance, as needed.

Final Rule Action: We are finalizing the revisions to the drug designation process regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration, that is, new injectable, intravenous, oral, or other form or route of administration,” that are “used to treat or manage a condition(s) associated with ESRD.” We are finalizing a revision at § 413.234(a) to the term we are defining, from “new renal dialysis drug or biological” to “new renal dialysis drug or biological product” to be consistent with FDA nomenclature. We are also finalizing the definition for “new renal dialysis drug or biological product” in § 413.234(a) to encompass the broader scope of the drug designation process with three revisions. First, we are revising the timing of the FDA approval to begin January 1, 2020, for consistency with our decision to finalize the policy for the TDAPA expansion with an effective date of January 1, 2020, for the reasons discussed in detail in section II.B.1.d of this final rule. This delay will provide an opportunity to engage in education and coordination with other CMS programs, including Medicare Parts C and D and Medicaid. The second revision is to refer to “biological product,” which is FDA’s preferred nomenclature, within the definition instead of “biological.” The third revision is to reflect the defined term “oral-only drugs” in § 413.234(a). Therefore, a new renal dialysis drug or biological product “must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020 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 are excluded until January 1, 2025.”

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 rulemaking regarding the eligibility criteria for the TDAPA. For example, commenters stated that they believed the drug designation process was too restrictive, could hinder innovation, and prevent new treatment options from entering the marketplace, and that CMS should contemplate the cost of new drugs and biological products that fall within the ESRD PPS 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.

As described in the CY 2016 ESRD PPS final rule, 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 (80 FR 69017 through 69024). For example, 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. The commenter pointed out that the functional categories are very comprehensive and capture every known condition related to ESRD. The commenter indicated that under the proposed approach to TDAPA, 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 suggested 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 (80 FR 69020).

An organization of home dialysis patients commented 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 (80 FR 69022). 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 ESRD PPS base rate. We interpreted the comment to mean 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 patients have the opportunity for better care, choices and treatment.

A national dialysis patient advocacy organization explained that if new products are immediately added to the ESRD PPS bundle without additional payment it would curtail innovation in treatments for people on dialysis. The organization believed clinicians should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes, and that the CY 2016 ESRD PPS 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 CY 2016 ESRD PPS proposed rule, reimbursement and

contracting arrangements could instead dictate utilization of a product before real world evidence on patient outcomes is ever generated (80 FR 69021).

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

A national dialysis organization strongly recommended that CMS adopt the same drug designation process for all new drugs and biological products (as opposed to only those that do not fall within a functional category) unless they are substantially the same as drugs or biological products currently paid for under the ESRD PPS payment rate. For new drugs or biological products that are substantially the same as drugs or biological products 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 product. The organization believed if the rate is inadequate to cover the cost of the new drug then the TDAPA should apply (80 FR 69016 through 69017). An LDO stated that, if implemented, the proposed drug designation 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 CY 2016 ESRD PPS proposed rule, the ESRD PPS base rate would remain stagnant. The commenter stated 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, although more clinically effective, drug.

A dialysis organization and a professional association asked 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 (80 FR 69019). An LDO stated that defining new drugs requires special consideration of cost. The LDO 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 (80 FR 69020).

Other commenters referred to pathways in other payment systems that provide payment for new drugs and biological products 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 that we should decouple the TDAPA from the functional categories and provide the additional payment for all new injectable and intravenous drugs and biological products and oral equivalents for 2 to 3 years, similar to the IPPS or the OPPS (80 FR 69020).

f. Expansion of the TDAPA Eligibility Criteria

As we discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34313 through 34314),

we continue to believe that the drug designation process does not prevent ESRD facilities from furnishing available medically necessary drugs and biological products to ESRD beneficiaries. Additionally, our position has been that payment is adequate for ESRD facilities to furnish new drugs and biological products 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 adjustment add-ons or outlier payments. In addition, 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 biological products 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 and that newer drugs may be more costly (80 FR 69021). Consequently, in the CY 2019 ESRD PPS proposed rule, we discussed a number of reasons why we were reconsidering our previous policy on the drug designation process.

First, we recognized the unique situations identified by the commenters discussed in section II.B.1.e of this final rule, and how they are impacted by the eligibility criteria for the TDAPA. We stated that 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, we noted that subsequent to the issuance of the CY 2016 ESRD PPS final rule, we continued to hear concerns that the drug designation process is restrictive in nature; and received requests from the dialysis industry and stakeholders that we reconsider the applicability of the TDAPA.

We acknowledged that ESRD facilities have unique circumstances with regard to implementing new drugs and biological products 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 biological products 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 noted that we agreed this uptake period would be best supported by the TDAPA pathway because it would help facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We stated that the TDAPA provides flexibility and targets payment for the use of new renal dialysis drugs and biological products 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 final rule, the ESRD PPS base rate includes dollars allocated for drugs and biological products 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 explained in the CY 2019 ESRD PPS proposed rule that we believe we need to be conscious of ESRD facility resource use and the financial barriers that may be preventing uptake of innovative new drugs and biological products that, while are already accessible to them, may be under-prescribed because the new drugs are priced higher than currently utilized drugs (as recommended by commenters). Therefore, we proposed that beginning January 1, 2019, we would add § 413.234(b)(1)(i), and (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 biological products, regardless of whether or not they fall within an ESRD PPS functional

category. New renal dialysis drugs and biological products 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 proposed to revise § 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 proposed to revise § 413.234(c)(1) to reflect that for new renal dialysis drugs and biological products that fall within a functional category, the TDAPA would apply for only 2 years. We explained that while we would not collect 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 we believed that this timeframe is adequate for payment. We also noted that we believed 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, we stated that 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 biological products into their standards of care and this could be supported by a transition period. Also, we noted that providing 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 biological products a foothold in the

market so that when the timeframe is complete, they are able to compete with the existing drugs and biological products 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 stated that we believed 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 noted 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 biological products in the past. We stated that we understand there are new drugs and biological products 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 noted that we would continue to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biological products that qualify. We stated that we would address any concerns through future refinements to the TDAPA policy.

We also proposed that when a new renal dialysis drug or biological product 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 an outlier payment. However, as discussed in section II.B.1.h of this final rule, if the new renal dialysis drug or biological product is considered to be a composite rate drug, it would not be eligible for an outlier payment. The intent of the TDAPA for a new renal

dialysis drug or biological product that falls within an existing functional category 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 explained that it would not be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories and that doing so 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 explained that the proposal to make no change to the base rate at the end of the TDAPA period for new renal dialysis drugs and biological products 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. We also noted that this proposal would 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 proposed 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 solicited comment on this proposal.

We proposed to operationalize this proposed policy no later than January 1, 2020. We stated that this deadline would provide us with the appropriate time to prepare the necessary

changes to our claims processing systems.

We solicited 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 biological products regardless of whether they fall within a functional category. Then, for a new renal dialysis drug or biological product 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 also solicited comment on the appropriateness of the 2-year timeframe for the TDAPA for new renal dialysis drugs and biological products that fall within existing functional categories.

We note that the nature of these proposals was to expand the applicability of TDAPA to new renal dialysis drugs and biological products that fall within an ESRD PPS functional category since we had already established a policy in the CY 2016 ESRD PPS final rule regarding the applicability of TDAPA to new renal dialysis drugs and biological products that do not fall within an ESRD PPS functional category. Therefore, the purpose of the proposal was supporting innovation, but geared solely toward those drugs and biological products that are considered reflected in the ESRD PPS base rate.

The CY 2019 ESRD PPS proposed rule did not propose any changes with regard to how CMS determines if a new renal dialysis drug or biological product is reflected in the ESRD PPS base rate. That is, we did not propose a change in the basic structure of the drug designation process, which is based on the ESRD PPS functional categories. New renal dialysis drugs and biological products that fall within an existing functional category are considered to be reflected in the ESRD PPS base rate. As proposed, the purpose of providing the TDAPA for these drugs that fall into an existing functional category is to help ESRD facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional

payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories. New renal dialysis drugs and biological products that do not fall within an existing functional category are not considered to be reflected in the ESRD PPS base rate, and the purpose of TDAPA for those drugs is to be a pathway toward a potential base rate modification.

We received many comments on the proposed revisions to the drug designation process regulations from all sectors of the dialysis industry, and each had their view on the direction the policy needed to go to support innovation. Commenters generally agreed that more drugs and biological products should be eligible for the TDAPA, that is, they agreed that drugs and biological products that fall within a functional category should be eligible for a payment adjustment when they are new to the market. However, the commenters had specific policy recommendations for each element of the drug designation process. Specifically, we received comments regarding which drugs should qualify for the TDAPA, the duration of the application of the adjustment, post-TDAPA base rate modifications, and basis of payment for the TDAPA. While a couple of commenters cautioned against implementing any changes in the drug designation process, overall, the general consensus from commenters was to expand the payment adjustment to new renal dialysis drugs and biological products that fall into an existing functional category and have clinical value with the intent to modify the ESRD PPS base rate, if applicable.

The comments and our responses to the comments on our proposals regarding the expansion of the TDAPA eligibility criteria are set forth below.

Comment: Two commenters supported the proposals. A professional association expressed support for CMS's efforts to foster innovation of new renal dialysis drugs and

biological products by revising its TDAPA policy and recommended that CMS keep the special needs of children with ESRD in mind and consider policies to foster the innovation of new therapies for this population.

A drug manufacturer supported CMS' flexibility and willingness to consider new approaches to improve access to innovative medicines. The commenter stated that CMS' proposed expansion of TDAPA eligibility will incentivize competition and innovation that encourages quality and cost-savings. The commenter appreciates CMS's acknowledgement of and willingness to take action to address uptake in innovations in treatment for ESRD patients through changes to the TDAPA for new drugs. The commenter also stated that these proposals encourage renal dialysis providers to consider the appropriate use of new drugs and biological products to improve the outcomes of their patients.

Response: We appreciate the support of the stakeholders.

Comment: Two commenters did not support the proposals. MedPAC expressed concern about the importance of maintaining the structure of the ESRD PPS and not creating policies that would unbundle services covered under the ESRD PPS or creating incentives that encourage high launch prices of new drugs and technologies. MedPAC stated that access to new dialysis products is favorable under the ESRD PPS. For example, in 2015, nearly one-quarter of all dialysis beneficiaries received epoetin beta, which was introduced to the U.S. market in that year. Consequently, MedPAC recommended that CMS should not proceed with its proposal to apply the TDAPA policy to new renal dialysis drugs that fit into a functional category (including composite rate drugs, which have never been paid separately by Medicare) for the following reasons:

- Although new dialysis drugs could improve patient outcomes, the proposal does not require that the new drugs be more effective than current treatment to qualify for the TDAPA.
- Paying the TDAPA for new dialysis drugs that fit into a functional category would be duplicative of the payment that is already made as part of the ESRD bundle. Beneficiaries and taxpayers already pay for drugs in each functional category because they are included in the ESRD PPS payment bundle.
- Applying the TDAPA to new dialysis drugs that fit into a functional category undermines the competition with existing drugs included in the PPS payment bundle. By bundling drugs with similar function together, CMS encourages providers to make decisions about each drug's clinical effectiveness for individual patients while also attempting to constrain costs. MedPAC pointed out that it has documented the changes in drug use due to increased price competition with the vitamin D and ESA therapeutic classes in both its 2016 and 2018 Reports to the Congress. MedPAC asserted that finalizing the TDAPA proposal would unbundle all new dialysis drugs, removing all cost constraints during the TDAPA period and encouraging the establishment of high launch prices. MedPAC explained that under the proposal, after the 2-year TDAPA period concluded, the new, potentially high-priced dialysis drugs would be included in the PPS payment bundle and could thereby further increase dialysis spending through the periodic process of rebasing the ESRDB market basket.

- The proposed policy would increase spending for beneficiaries and taxpayers, as CMS acknowledges. However, the proposed rule did not include an estimate of expected spending changes in the “detailed economic analysis” section.

An LDO also did not support the TDAPA proposal. The commenter explained that it has observed significant issues for both patients and providers under the current TDAPA program, which support delaying expansion until the process can be better evaluated. The commenter further explained that under the TDAPA, patients will experience substantial increases in cost-sharing, as these drugs will be subject to Part B’s 20 percent co-insurance, instead of being part of the PPS bundle. The commenter pointed to its experience under the current TDAPA period for calcimimetics, stating that this cost-shifting to vulnerable ESRD patients has had a detrimental effect on them, as many have had to refuse necessary medications due to their high costs. In addition, the commenter stated that providers frequently provide the medications to patients and then are unable to fully recoup the 20 percent coinsurance from them, resulting in considerable amounts of unreimbursed bad debt, which places additional burden on dialysis facilities.

This LDO identified other significant issues encountered by patients and providers including revenue loss from the inability to bill Medicare for full prescriptions; payers not recognizing an oral medication under the medical benefit; Medicare paying for drugs consumed, for which dialysis facilities have little to no visibility, and not for drugs dispensed (a particular problem for oral drugs); payers experiencing system update problems that have resulted in incorrect or no reimbursement for current medications subject to TDAPA; lack of Medicaid secondary coverage for Medicare primary patients; pricing power shifting to pharmaceutical manufacturers; and an absence of reimbursement from Medicare Advantage plan contractors.

Some commenters used their experience with the current TDAPA policy to express that due to the difficulties related to the transition of oral drugs from payment under Medicare Part D to Medicare Part B, CMS should obtain 2-full calendar years of claims data before engaging in rulemaking to incorporate the new drug or biological product into the ESRD PPS bundled payment. Again, referring to calcimimetics as the example, the commenters stressed how important it is for dialysis facilities to receive timely and clear clinical and billing guidance. A national LDO organization stated the current policy creates a disconnect between oral calcimimetics, which are prescribed for daily use, including days that do not include a dialysis treatment, and the per treatment payment methodology. The LDO stated this disconnect can result in dialysis facilities being unable to claim all the days when the patient took the oral calcimimetic.

The LDO also stressed that further steps are needed to address confusion among plans regarding their coverage and payment responsibilities for new renal dialysis oral drugs under the MA program. The commenter further explained that CMS needs to take additional action to ensure that all MA enrollees with ESRD have good access to the drug formulation that meets their needs by issuing guidance that reiterates coverage and reimbursement for these drugs.

The LDO further stated that it is premature to expand the TDAPA before data and experience from the first period is analyzed and thoughtfully considered, and strongly recommended that CMS not move forward on expanding TDAPA at this time. While the organization stated that it supports and encourages CMS's interest in developing a process to incentivize significant innovation in dialysis treatment, the organization believes the proposal may undermine investment in treatment advances that significantly improve outcomes or quality of life for vulnerable patients.

Response: We understand and appreciate the concerns expressed by the commenters.

With regard to MedPAC's concern that the proposal does not require that the new drugs be more effective than current treatment to qualify for the TDAPA, we believe that allowing all new drugs to be eligible for TDAPA will provide an opportunity for the new drugs to compete with other similar drugs in the market which could mean lower prices for all drugs. We believe drug manufacturers understand that if they are to compete with drugs currently in the ESRD PPS bundle, they need to not only be better, but they also must come in at a lower price in order to continue to be utilized by the facilities in the post-TDAPA period. The 2-year TDAPA period gives the innovative product an opportunity to demonstrate its clinical value and financial worth, while buffering the risk to both the manufacturer and the facility. If the facility finds the product sufficiently worthy of use among its patients, then the manufacturer has an incentive to keep the price lower than the drug it is replacing that is currently in the bundle. In addition, the effectiveness of drugs can depend on age, gender, race, genetic pre-disposition and comorbidities. Innovation can provide options for those that do not respond to a certain preferred treatment regimen the same way the majority of patients respond. However, we appreciate MedPAC's feedback and will consider the comment for future refinements to the TDAPA policy.

With respect to MedPAC's concern regarding duplicate payment for new drugs that fit into a functional category, as noted previously, we believe the TDAPA would help facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition among other drugs and biological products in the same ESRD PPS functional categories. We do not view the expanded TDAPA as duplicative payment because at the end of the TDAPA time

period, there is no additional money added to the base rate for those drugs that already fall within functional category. This TDAPA is a separate, temporary payment adjustment for the reasons discussed above. We believe the TDAPA expansion will encourage innovative products to come into the market, by facilitating the introduction of more drug options to the functional categories. We also believe this TDAPA expansion will enhance treatment options for those population subsets that currently may not respond optimally to what is available in the bundle. We have heard from ESRD facilities that newer drugs may carry higher financial risk for the centers due to inventory issues with higher cost drugs, and this may cause uneven access to the newer products. We note that the TDAPA for new drugs considered to be included in the functional categories would be temporary. In addition, we believe that in order for the new drugs to obtain a long-term market share, they will need to show better clinical results and be available at a competitive price once those drugs are bundled into the ESRD PPS. Some of the drugs currently in the bundle effectively target a specific condition but have side effects that manifest themselves differently across the population of ESRD patients. If a third or fourth generation product achieves the same clinical effect, and does not have those side effects, then it would be a clinically superior product for that population.

With regard to MedPAC's assertion that finalizing the TDAPA proposal would unbundle all new dialysis drugs, remove all cost constraints during the TDAPA period and encourage the establishment of high launch prices, we believe that we are mitigating these issues by paying ASP+0 for a limited amount of time (2 years) and by not making modifications to the base rate. If manufacturers choose to respond with an even higher launch price, then there is a possibility their product will not be used as much because the beneficiary co-pays will also be increased. This could increase bad debt for the facilities. We believe as stated above that our policy could

lead to lower drug prices during the TDAPA period and once the TDAPA period expires. We note that TDAPA is a *transitional* payment, and under this expansion does not result in a permanent addition to the base rate. Rather, this payment will help facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition with other drugs and biological products within the same ESRD PPS functional categories. We believe paying the TDAPA for all new drugs will foster competition, and actually encourage the companies with existing drugs in the functional categories to produce a newer, better product, at a lower cost in order to retain their market share.

With regard to MedPAC's concern regarding the ESRDB market basket rebasing, we believe that any impact that would result from the proposed TDAPA expansion is unknown at this time. We will continue to monitor the impact that these changes have on the relative cost share weights in the ESRDB market basket, over time, as reported in cost report data. When appropriate we will rebase the ESRDB market basket to reflect observed shifts in cost weights.

In response to MedPAC's comment that we did not include an estimate of expected spending changes in the "detailed economic analysis" section for the proposal, we were unable to provide such impacts because the policy addresses drugs and biological products that have not been developed and therefore we would not be able to address hypothetical usage and project impacts accurately.

With regard to the comments about beneficiary coinsurance, we acknowledge there will be increases; however, we believe that access to innovative new drugs that could provide better clinical outcomes and fewer side effects will be valuable to beneficiaries and help to offset the coinsurance obligation. In addition, we believe drug pricing information and coinsurance

amounts should be a part of the discussion between the beneficiary and his or her physician regarding the decision to use new drugs. For this reason, we believe that concerns about what beneficiaries have to pay for coinsurance and whether ESRD facilities are able to obtain these payments from other payers versus directly from the ESRD beneficiary, would have an impact on the drugs that are used for treatment.

We are finalizing the expansion of TDAPA to encourage development of new drugs within the current functional categories. However, we understand and acknowledge the concerns expressed by the LDO about operational difficulties and patient access issues experienced for the current drugs paid for using the TDAPA. In recognition of those concerns, we are making the changes to the drug designation process under § 413.234 and the expansion of TDAPA eligibility effective January 1, 2020, as opposed to January 1, 2019, to address as many of those concerns as possible. We believe that the small dialysis organizations and rural facilities have a more difficult time developing processes than LDOs, and delaying the effective date of the expansion of TDAPA by 1 year would benefit both types of facilities. This additional year would also provide us with the opportunity to address issues such as transitioning payment from Part D to Part B, and coordination issues involving Medicaid and new Medicare Advantage policies. Finally, the additional year will allow more time for provider and beneficiary education about this new policy.

In addition, regarding the previous discussion on HCPCS codes, we will need to work with the current HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new drugs and biological products. In collaboration with the HCPCS workgroup we will make the determination of whether a drug or biological product is a renal dialysis service. We will also determine if the new renal dialysis drug or biological product falls within an existing

functional category or if it represents a new functional category. We discuss the operational concerns that warrant a 1-year delay of the TDAPA expansion in section II.B.1.f of this final rule.

Comment: A national kidney organization, a national dialysis association, a clinical association, a dialysis provider organization, as well as drug manufacturers, expressed support for the application of TDAPA to all new drugs and biological products approved on or after January 1, 2019, but they recommended that CMS not apply TDAPA to generic drugs or to biosimilars. The commenters explained that they believe the rationale for TDAPA is to allow the community and CMS to better understand the appropriate utilization of new products and their pricing. The commenters asserted that generic drugs and biosimilars seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Thus, the additional time is unnecessary for these drugs and biological products.

A drug manufacturer further stated that a generic drug clearly is not innovative because it must have the same active ingredient, strength, dosage form, and route of administration as the innovator drug; a biosimilar also is not innovative because it is required under statute to be highly similar and have no clinically meaningful differences to the reference product and must be administered in the same manner to treat the same conditions that the reference product is licensed to treat. The commenter stated that because they have no clinically meaningful differences, biosimilars and reference products should be treated equally in payment and coverage policies; a biosimilar should not be eligible for the TDAPA when its reference product would not qualify for the payment.

A different drug manufacturer made a similar comment and stated that while it appears clear that the proposal would exclude generic drugs, it appears to allow biosimilars to receive

TDAPA. The commenter stated that it does not believe biosimilars need to be treated differently than generic drugs and recommended that CMS not extend TDAPA to these products as those dollars would be better spent adjusting the bundled rate to ensure adequate funding for truly innovative products.

Response: We proposed to allow all new drugs in current functional categories, including generic drugs, and biosimilar biological products approved under 351(k) of the PHS Act, to receive the TDAPA because we want to foster a competitive marketplace in which all drugs within a functional category would compete for market share. We believe this will mitigate or discourage high launch prices. We believe including generic drugs and biosimilar biological products under the TDAPA expansion will foster innovation of drugs within the current functional categories. We also believe including these products will give a financial boost to support their utilization, and ultimately lower overall drug costs since these products generally have lower prices. Because of this, generic drugs and biosimilar products will provide cost-based competition for new higher priced drugs during the TDAPA period and also afterward when they are bundled into the ESRD PPS.

Comment: Some commenters also recommended that CMS require that the new renal dialysis drug or biological have a clinical superiority over the existing drugs in the bundle and provided suggestions on clinical value criteria. For example, several commenters indicated that the following are examples of when a new drug has high clinical value:

- Drugs and biologicals that fill a treatment gap (address an unmet medical need) in an existing functional category;
- Drugs or biologicals that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug's label;

- Drugs or biologicals for which there are multiple clinical outcomes as stated in the FDA labeling material approved by the FDA (including within the clinical pharmacology and study portion of the label approved by the FDA);
- Drugs and biologicals that are approved by the FDA (if appropriate to add to a functional category based on the indications listed in FDA-approved labeling) that have demonstrated clinical superiority to existing products in the bundle; or
- Drugs and biologicals that improve priority outcomes, such as:
 - ++ Decreasing hospitalizations;
 - ++ Reducing mortality;
 - ++ Improving quality of life (based on a valid and reliable tool);
 - ++ Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);
 - ++Addressing patient-centered objectives (including patient reported outcomes once they are developed and assessed by the FDA in its review of drugs and biologicals);
 - ++Reducing in side effects or complications; or
 - ++Drugs and biologicals that have a significantly better safety profile than existing products.

An LDO recommended that CMS limit TDAPA to significantly innovative drug products that substantially advance the treatment and management of conditions associated with ESRD or have demonstrated safety advances. The LDO requested the opportunity to work with CMS and interested stakeholders to develop a uniform definition of significant innovation.

Response: We believe that allowing all new drugs and biological products to be eligible for the TDAPA will provide an ability for new drugs to compete with other drugs in the market,

which could mean lower prices for all drugs. We further believe, categorically limiting or excluding any group of drugs from TDAPA would reduce the competitiveness because there would be less incentive for manufacturers to develop lower-priced drugs, such as generic drugs, to be able to compete with higher priced drugs during the TDAPA period. In addition, the question of drugs being more effective can be subjective since effectiveness of drugs can depend on age, gender, race, genetic pre-disposition and comorbidities. Innovation can provide options for those patient who do not respond to a certain preferred treatment regimen the same way the majority of patients respond. However, we appreciate the commenters' feedback and will consider these suggestions for future refinement of the drug designation process.

Comment: A patient advocacy organization applauded the revisions to the drug designation process regulations and stated that while any innovations in treatment that improve quality of life or tolerability of dialysis have great value to patients, they do not support adding dollars to the base rate for more expensive "me-too" substitute drugs or biological products that add no value for patients or for the Medicare program.

A dialysis provider organization also expressed concern that the proposed policy would encourage promotion of so called "me too" drugs and higher launch prices, even if moderated after 2 years. The organization stated that developers need to have a clear roadmap and set of criteria based on whether a new drug is a significant clinical improvement that warrants a higher cost to the program, and beneficiaries, as well as possible financial tradeoffs to providers. Rather than an open-ended policy, several commenters recommended that CMS consider a new drug policy more in line with those in other parts of the Medicare program, such as the policies for new technologies under the hospital inpatient PPS which includes a substantial clinical improvement test and for devices under the outpatient PPS.

Response: We understand drugs characterized as “me too” drugs are new drugs that are in the same product class as other drugs currently in the functional categories. We agree with the commenter that recommended not adding dollars to the base rate for more expensive “me-too” substitute drugs or biological products and note that we did not propose such a policy. However, we believe the introduction of new drugs in the functional categories promotes competition that lowers prices, while frequently improving on the quality of the first-in-class drugs.

With regard to the comment on significant clinical improvement, we did not propose this criteria because our goal was to be expansive regarding the applicability of TDAPA. In general, manufacturers compete on the basis of cost, and it is that competition that ignites negotiating. We believe when there is more than one choice of drug, ESRD facilities have the ability for bargaining, obtaining lower drug prices, and taking their drug needs to another manufacturer. When there is a monopoly by one drug company, the ability to bargain is removed. With respect to physicians, we note that those physicians prescribing drugs in the functional categories should not only be interested in their patient’s clinical well-being and safety, but also take into consideration the patient’s financial resources.

With regard to other Medicare payment systems, although the systems are noteworthy, under the ESRD PPS there is a different programmatic approach to new drugs and biological products. We believe the TDAPA would apply for more new drugs and biological products than if we utilized a policy similar to the other payment systems. Under the final policy, the expanded TDAPA will apply to all new renal dialysis drugs and biological products and will be paid for 2 years, and these drugs and biological products will not need to meet clinical improvement or cost criteria. In addition, our goal in this approach is to assist ESRD facilities in incorporating these products and promote development of new renal dialysis drugs and

biological products to compete with other drugs in the ESRD PPS functional categories with the aim of lowering drug prices.

Comment: A drug manufacturer recommended that CMS consider when the FDA may re-profile a drug. The commenter further explained that re-profiling a drug may occur when its utility and efficacy are further elucidated or expanded once on-market. The commenter recommended that CMS establish a pathway as part of the drug designation process that would allow for manufacturers or other stakeholders to request that CMS reconsider how a particular drug is classified with regard to the functional categories and, if appropriate, adjust the base rate when there is a change in the label approved by FDA.

Response: When the commenter discusses re-profiling, we presume the commenter is referring to the FDA's approval of changes to the labeling of already approved drugs to add new indications for additional diseases or conditions. Under the current ESRD PPS functional categories, in that circumstance the drug would be automatically included in the ESRD PPS bundled payment amount when it is identified as a renal dialysis service based on its FDA approved labeling. We appreciate this feedback and will consider these recommendations for future refinements to the policy.

Comment: A drug manufacturer commented that it is vitally important that CMS does not exclude new drugs from TDAPA that have been FDA approved for the treatment of ESRD since the bundled payment became active in 2011. The commenter stated there is no basis for excluding these drugs, and pointed out that Triferic is the only drug CMS would need to consider during that time period because CMS approved the TDAPA for the other drug (calcimimetics). The commenter stated that excluding this one drug from TDAPA would be unfair and prevent patients from gaining access to a new innovative therapy that is available and can improve their

lives.

Response: We generally are precluded from retroactively implementing regulations and therefore, we are unable to provide TDAPA payments for new drugs approved by the FDA since 2011. We apply the policy that was in effect when the drug is launched which, in the case of Triferic, was to provide no add-on payment for drugs in the existing ESRD PPS functional categories beyond the ESRD PPS bundled payment amount.

The next set of comments and responses address the proposal regarding the 2-year duration of TDAPA for new renal dialysis drugs and biological products that fall within a functional category. Commenters had two main concerns with this aspect of the proposal. First, commenters were concerned with how long ESRD facilities would receive the payment adjustment. Second, commenters wanted clarification on the specific timeframe CMS would use to evaluate utilization for rate-setting purposes.

The comments and our responses to the comments on this proposal are set forth below:

Comment: Many commenters suggested that CMS retain the flexibility to extend the TDAPA period beyond 2 years to ensure that accurate and complete data are available to make determinations about bundling new products and adjustments to the bundled rate. One commenter noted that a “new” drug or biological product that falls within an existing functional category, including composite rate drugs, could be one that has a relatively familiar mode of action in the body to drugs and biological products that are already included in this category. This type of drug could be appropriate for a 2-year TDAPA period, however, if the “new” drug or biological product has an entirely new mode of action with which clinicians are unfamiliar (including but not limited to new benefits, side-effects, or safety profile) that product could deserve a longer TDAPA period. The commenters explained that if the language in the drug

designation regulations stated “at least two years,” consistent for both existing functional category drugs and new functional category drugs and biological products, CMS would maintain the flexibility to use a 2-year period in those instances where there is sufficient claims data to move a drug or biological product into the bundle, but also have the ability to extend that period when warranted.

A few commenters requested for CMS to clarify it will evaluate at least 24-consecutive months of claims data prior to bundling any new drug or biological product into the ESRD PPS.

A drug manufacturer recommended the TDAPA apply for 3 years to better protect access to new drugs and to increase the amount of data collected for rate setting. The commenter explained that when a new drug becomes available, it can take months for dialysis facilities to incorporate it into their treatment protocols and implement the required changes in coding and billing to reflect use of the drug on their claims. A national provider association supported this statement and described situations that can slow the rate of uptake of new products. For example, this commenter stated that physicians, nurses and administrative staff must receive education and training from the drug manufacturer so that the drug or biological product can be safely and effectively administered. Eligible patients must receive education on the medication prior to prescription and administration. The facility staff must review all patient insurance plans to initiate the authorization process to start the new drug. And, facilities must negotiate with vendors for the supply and pricing of the item so it can be purchased and administered to patients. The commenter further explained that the particular acuity and severity of the ESRD patient population generally results in facilities more gradually increasing use of novel therapies in these patients over time.

One commenter explained that due to the length of the rulemaking cycle, CMS typically

has a 1-year lag between collecting claims data and implementing any reimbursement changes based on that data. The commenter asserted that if CMS extended a drug's TDAPA beyond 2 years, it would have more than 1 year of data available to use to adjust the base rate, and those data would be more likely to reflect mature utilization patterns in clinical practice. In addition, the commenter noted that when a drug does not qualify for an adjustment to the base rate, a longer TDAPA period would give facilities more time to determine how to accommodate use of the drug under the base rate.

A different drug manufacturer and a clinical association recommended that CMS apply TDAPA for whatever the period of time required to obtain 2 full years of claims data, not just 2 calendar years. The commenters explained that while they appreciated the concern noted in the preamble to the proposed rule that a longer TDAPA period “could improperly incentivize high cost items without more value,” they believed 2-calendar years of TDAPA would not provide adequate data to assess the information CMS has identified is necessary when new drugs come to market. They further explained that it is also important to have 2-full years of claims data to assess whether a new renal dialysis drug or biological product should be added to the bundle (or alternatively an add-on or adjuster be used to account for drugs not used in the average patient) and, if so, whether new dollars should be added to the base rate as well. They stated that depending on the variability in the prescribing protocols and general uptake in utilization, the data available at the end of 2-calendar years would not provide an adequate picture of utilization or cost.

A drug manufacturer and a national dialysis association noted that both CMS and Congress have recognized the need for a longer transitional payment period than 2 years for new drugs in the OPPS setting. They explained that while initially pass-through payment for new

drugs was provided for 2 years, the period was extended by CMS in 2017 to 3 years. The commenters also indicated that in the Bipartisan Budget Act of 2018, Congress extended the pass-through period for certain outpatient drugs for an additional 2 years beyond the 3-year period CMS had implemented. The drug manufacturer estimated that the TDAPA period could be needed for up to 4 years to collect 2 full calendar years of claims data.

An LDO indicated that sufficient time is needed to evaluate new drugs as they come onto the market and also recommended that CMS obtain 2 full calendar years of claims data. The commenter recalled its experiences with an ESA and an iron replacement therapy product to illustrate concerns that may arise during the transition period. The commenter explained that since phase 3 studies are small, adverse events may not be recognized until a promising new drug is more widely used. The commenter went on to describe its experience with specific new drugs, identifying a higher rate of adverse effects in comparison to other products for these drugs, which resulted in its medical directors recommending discontinuing use of the drugs.

Response: In expanding TDAPA to new renal dialysis drugs and biological products that fall within the existing ESRD PPS functional categories, we did not propose to incorporate these drugs into the ESRD PPS base rate when the TDAPA period ends. Rather, we proposed to apply TDAPA for 2 years to support access to the new drug during its uptake period. The purpose for this expanded TDAPA is to help ESRD facilities incorporate these drugs and foster competition and innovation for ESRD drugs. At the end of the TDAPA period, we expect that the drug would achieve its foothold and would be able to compete with other drugs in the functional category. We continue to believe providing TDAPA for 2 years is appropriate for drugs in the current functional categories and that a longer timeframe to establish the drug's utilization is not necessary for drugs in a functional category, particularly since the ESRD PPS payment includes

money for the drugs in these categories. With respect to the specific recommendation that we collect sufficient claims data, there is no data collection period for new renal dialysis drugs and biological products that fall within the existing functional categories for the purpose of modifying the base rate. However, we monitor utilization of all items and services available under the ESRD PPS. We will also use claims data to monitor for increased costs related to use of the new TDAPA drugs. We are not expanding the duration of TDAPA for these drugs because we believe that 2 years strikes the appropriate balance of supporting innovation while protecting the Medicare Trust Fund.

Under our final policy, beginning January 1, 2020, for new renal dialysis drugs and biological products that fall within an existing functional category, the application of TDAPA will begin with the effective date of subregulatory billing guidance and end 2 years from that date.

For new renal dialysis drugs and biological products that do not fall within an existing functional category, the application of TDAPA will begin with the effective date of subregulatory billing guidance and end after we determine, through notice-and-comment rulemaking, how the drug will be recognized in the ESRD PPS bundled payment.

The next set of comments and responses address our proposal that when a new renal dialysis drug or biological product falls within an existing functional category, at the end of the TDAPA period, we would not modify the ESRD PPS base rate. In general, commenters expressed that there is a need to consider a base rate modification for all new renal dialysis drugs and biological products to support their long term use. The comments and our responses to the comments on this proposal are set forth below:

Comment: We received several comments expressing concern that the functional

categories are too broad to be the determining factor for when a drug or biological product is included in the ESRD PPS bundled payment. A national dialysis association asserted that the distinction CMS has drawn between drugs and biological products within an existing functional category, including composite rate drugs, and those outside an existing functional category is artificial and may not correspond to clinician, patient, or provider experience in the real world. The commenter recommended that all new renal dialysis drugs and biological products, regardless of functional category, should have its utilization and price patterns evaluated before decisions are made with regard to the ESRD PPS bundled payment. The commenter believes CMS should consistently apply the review of utilization prior to making decisions about bundling drugs and biological products because this ensures that the bundling of a drug or biological product is based on the actual review of real and reliable data.

Several commenters, including a national dialysis association, noted that there are several new drugs in the pipeline that are not generic drugs or biosimilars and, while likely to have an indication for which a product is labeled and approved focused on treating conditions in an existing functional category, will not be clinically substituted with drugs currently in the functional categories or will provide a more effective treatment option, that is, true innovations. The national dialysis association stated that while current funding within the ESRD PPS may be sufficient to cover the costs for some new drugs or biological products within an existing functional category, it may not be sufficient for all new drugs and biological products. For these other drugs and biological products, the commenter noted, having guaranteed access to the TDAPA is only part of the solution. The association stated that innovation requires appropriate and sustainable long-term funding as well.

The commenters stated if CMS were to adopt a blanket policy of not adding new money

to the bundle for any drug or biological product that comes within one of these categories, it will stifle innovation and leave patients with the same standard of care that existed in the 1990s. The commenters noted that unless there is adequate reimbursement for new products, they simply will not be used. Patients will lose access to them, even if these products are used during the TDAPA period. A drug manufacturer with a similar concern explained that if the cost will not be covered afterward in the bundle or via some other payment mechanism, it is highly likely that a dialysis facility will not convert to the new therapy with just 2 years of TDAPA. Commenters noted that an investment in what could be a temporary payment adjustment could adversely affect the financial aspects of the company, and may affect prescribing decisions after the TDAPA period.

A patient advocacy organization disagreed with our statement in the proposed rule that adding dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories would be in conflict with the fundamental principles of a PPS and stated that a treatment that provides either longevity gain or improves quality of life or tolerability of treatment has great value to patients and is worthy of increased reimbursement. The commenter stated that if there is a colorable claim that a new treatment adds value, the cost of that treatment should be built into the base rate for year 3 while further developing evidence. Then, if the claims prove exaggerated and the new drug or biological product falls into disuse, CMS would have the option of reducing or eliminating the additional expenditure.

While many commenters suggested that CMS implement a rate-setting exercise at the end of TDAPA for all new renal dialysis drugs and biological products, other commenters expressed concern that we would add dollars to the base rate for drugs and biological product without

significant clinical value. Given that new drugs for dialysis patients are expected in 2019, some commenters encouraged CMS to develop a final rule with comment period, that describes the process and criteria it will use to evaluate drugs for functional category consideration and determine when additional money will be added to the bundle, particularly when the drug is considered a significant clinical improvement over existing drugs.

Response: We appreciate the concerns raised by the stakeholders with regard to our proposal to not adjust the base rate after the end of the TDAPA period for new drugs or biological products that fall within an existing ESRD PPS functional category. We continue to believe that because the existing functional categories account for renal dialysis services in the ESRD PPS bundled payment, 2 years is long enough to be meaningful and to allow these new drugs to gain a foothold in the market, but not too long as to improperly incentivize high cost items without added value, for example, substitutions of those drugs that already exist in the functional category. The functional categories were designed to be broad because, when a new drug becomes available, it is added to the therapeutic armamentarium of the treating physician.

With regard to the commenter stating that CMS should consider continuing the TDAPA for a third year while developing further evidence, we do not intend to modify the base rate for new renal dialysis drugs and biological product in existing functional categories. With regard to the longevity gain, we do not believe that 2 years would provide the experience to assess longevity, and further, the intent of the TDAPA for new drugs is to be a short term payment to help facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition with other drugs and biological products within the same ESRD PPS functional categories. Regarding the suggestion that increasing the base rate would be in keeping with the

purpose of the ESRD PPS and would increase the quality of life of the ESRD beneficiary, we note that quality of life is a highly subjective determinant and is outside the purview of a PPS, however we believe this policy expands options which could enhance quality of life.

We are concerned about the comment stating that there will be beneficiary access issues at the end of the TDAPA period for new renal dialysis drugs or biological products that fall within a functional category. As we noted above, these drugs will be paid under the ESRD PPS bundle and become eligible under the outlier policy, if they are not considered to be a composite rate drug. We expect that if a beneficiary is responding well to a drug or biological product paid for using the TDAPA that they will continue to have access to that therapy after the TDAPA period ends. We plan to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biological products that qualify.

We appreciate the suggestion of undergoing a rate-setting exercise wherein we compare the dollars allocated to a functional category to the cost of the new drugs to determine if reimbursement is appropriate. However, we did not propose to modify the base rate for new drugs that fall into the functional categories given that the purpose of the TDAPA for these drugs is to provide a short term boost to help ESRD facilities implement these products and to support innovation. We will consider this suggestion in future rulemaking.

With regard to the functional categories, we note that they were established based on the drugs and biological products that were included in the ESRD composite rate or billed on claims in conjunction with a dialysis treatment when the ESRD PPS was developed. The functional categories are a mechanism for adding new drugs and biological products to the bundle and designed to capture all renal dialysis services. Since the PPS began, we have routinely and consistently monitored the utilization and pricing of all drugs furnished to ESRD patients and

will continue to do so as new drugs are developed. We appreciate the viewpoints expressed by the commenters and will take the comments into consideration.

Comment: An LDO noted that CMS characterized the proposed TDAPA expansion as a means to give new renal dialysis drugs and biological products footholds in the market so that they can compete with existing drugs and biological products. The LDO stated that it is naïve to conclude that after achieving a market foothold, a manufacturer would simply lower the cost of a drug or biological product whose development required additional financial support through the TDAPA. Rather, manufacturers will still have incentive to continue to recoup those development costs, giving them significant negotiating leverage over dialysis facilities. The commenter further explained that given that scenario and existing financial constraints, it will be difficult for dialysis facilities to offer such new drugs and biological products during the TDAPA period as well as after it expires.

Response: We appreciate this feedback, however we believe that the TDAPA will incentivize competition, which will ultimately lower drug prices after the TDAPA period since there will be more drugs available to treat each condition. We believe that having more drug choices in the existing functional categories will increase both the negotiating power for facilities and their ability to obtain a competitive price after the TDAPA period ends. For example, we believe it is reasonable to conclude that once a lower cost drug, such as a generic drug, obtains a market foothold that dialysis providers will embrace the opportunity to switch to that drug's lower cost while maintaining quality of care. Under the ESRD PPS, ESRD facilities are responsible for furnishing all renal dialysis services either directly or under arrangement. As noted previously, we will monitor the application of the TDAPA adjustment and utilization during the TDAPA period, along with the utilization of the drugs that qualified for TDAPA, after

the TDAPA period ends.

Comment: Several commenters suggested that we uniformly apply the TDAPA and provided suggestions on how CMS should recognize new renal dialysis drugs and biological products in the ESRD PPS bundled payment after the TDAPA period ends. For example, commenters recommended that CMS clearly state when a drug or biological product, even if it were to qualify for a functional category, will not be bundled if it is not provided to the average patient. The commenters referred to the language in the CY 2019 ESRD PPS proposed rule where CMS stated that “the bundle is based on the costs incurred by the average patient.” The commenters explained that if only a small portion of patients use the product, then it should not be added to the bundle because that would create the wrong incentives. The commenters further explained that providers who use the product will always be reimbursed less than it costs to provide the product and providers who do not use the product will receive a windfall (albeit a small one). The commenters asserted that bundling a product that is medically necessary for only a small percentage of patients only disincentivizes its use.

Response: We disagree with the commenter that the TDAPA should be applied uniformly, because the purpose of the TDAPA is different depending on whether the new drug or biological product falls or does not fall within an existing functional category. That is, if the new drug falls within an existing functional category, the purpose of the TDAPA is to support its uptake period. For new drugs that do not fall within an existing functional category, the purpose of the TDAPA is a pathway to a potential base rate modification. When we describe the PPS as a payment system based on the “average patient,” that means based on the costs of the average patient, not that the majority of patients utilize specific drugs, items, or services.

Comment: We received several comments expressing concern about the duration and

sufficiency of data collection for calcimimetics and requesting clarification from CMS. Several commenters questioned whether paying the TDAPA for 2 years means CMS would be making utilization and pricing decisions based on a year or less of data due to CMS's rulemaking cycle. They maintained that the first year of utilization is not reflective of how the new drug will actually be used, and expressed concern about the impact of the thus far low and uneven utilization of calcimimetics on the data and any subsequent pricing decisions. To determine the appropriate duration for data collection, a drug manufacturer urged CMS to first consider the rate at which dialysis facilities incorporate new drugs into their treatment regimens. Several commenters also requested that CMS work with ESRD stakeholders to develop the methods CMS will use to evaluate the data as well as an approach to accounting for calcimimetics in the base rate. The commenters want to ensure that beneficiaries continue to have access to these drugs once the TDAPA period ends. In particular, an LDO noted the importance of recognizing the uniqueness of the oral calcimimetic in that it is taken daily when the payment system is designed for 3 treatments per week. A few commenters specifically requested that CMS outline its methodology in this final rule, with a comment period.

Response: As we stated in the CY 2019 proposed rule (83 FR 34309 through 34310), under § 413.234(c), for new injectable or intravenous products that are not included in a functional category, 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. We note that this period begins with the effective date of a change request and, after at least 2 years of data collection, ends with rulemaking to modify the ESRD PPS base rate, if appropriate. After 2 years of data collection, we will evaluate the data, and if we determine that we need further data collection, we will

continue TDAPA payments until data collection is sufficient. We further thank the commenters for their suggestions of methods we should employ when evaluating the data. We will keep these in mind and will provide further discussion about our methods in future rulemaking.

Final Rule Action: After consideration of public comments, for CY 2019 we are finalizing the revisions to the drug designation process regulations to reflect the proposed policy but are delaying the effective date of the policy revisions until January 1, 2020. The purpose of the delay is to mitigate the launch issues of the TDAPA expansion particularly for CMS programs (HCPCS, Medicaid and Medicare Part C). Also, many state Medicaid programs offer the same scope of services available under Part C and may need additional time to ensure proper communication so that dual eligible beneficiaries have access to drugs receiving the TDAPA. In addition, states may need time to modify their systems to adopt new renal dialysis drugs and biological products. For stakeholders (particularly small dialysis organizations and rural facilities) we believe the delay will be beneficial so that they can adapt and streamline processes to support a seamless transfer between Agency programs when new drugs are launched and are eligible for the TDAPA. For example, facilities will have more time during this year to develop software to accommodate the diverse nature of all drugs receiving TDAPA so that they can be flexible and communicate with Medicare and Medicaid system requirements.

Specifically, we are finalizing the addition of § 413.234(b)(1)(i), (ii) and revision of § 413.234(c) with one revision to proposed § 413.234(b)(1)(ii), to reflect that the TDAPA, under the authority of section 1881(b)(14)(D)(iv) of the Act, will apply to all new renal dialysis injectable or intravenous products, oral equivalents, and other forms of administration drugs and biological products, regardless of whether or not they fall within a functional category, effective January 1, 2020. We also note the revision to refer to “biological product,” which is FDA’s

preferred nomenclature, within the definition instead of “biological”.

We are finalizing the revision of § 413.234(b)(2)(ii) and § 413.234(c)(2), removal of § 413.234(c)(3), and addition of § 413.234(c)(2)(i) to reflect that we will continue to provide the TDAPA, collect sufficient data, and modify the ESRD PPS base rate, if appropriate, for new renal dialysis drugs and biological products that do not fall within an existing functional category.

We are finalizing the revision to § 413.234(c)(1) to reflect that for new renal dialysis drugs and biological products that fall within a functional category, the TDAPA applies for only 2 years, effective January 1, 2020.

We are finalizing the addition of § 413.234(c)(1)(i) to reflect that when a new renal dialysis drug or biological product falls within an existing functional category at the end of the TDAPA period we will not modify the ESRD PPS base rate, but at the end of the 2 years, as consistent with the existing outlier policy, the drug is eligible for outlier payment, effective January 1, 2020. However, as discussed in section II.B.1.h of this final rule, if the new renal dialysis drug or biological product is considered to be a composite rate drug, it will not be eligible for an outlier payment.

Commenters did not specifically comment on the proposal to operationalize this proposed policy no later than January 1, 2020. Therefore, we are finalizing this proposal as proposed. We note that this action coincides with the delayed effective date to January 1, 2020 to better coordinate with CMS and stakeholders as noted above. For CY 2019, the current regulations (and drug designation process) will remain in place and will apply to new renal dialysis drugs and biological products that come on the market, but beginning January 1, 2020, the new regulations (and drug designation process) will take effect.

g. 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). As we explained in the CY 2019 ESRD PPS proposed rule (83 FR 3414), if we adopt the proposals discussed in section II.B.1.f of this final 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 biological products.

The TDAPA is a payment adjustment under the ESRD PPS and is not intended to be a mechanism for payment for new drugs and biological products 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 CY 2019, we considered options for basing payment under the TDAPA, for example, maintaining the policy as is and facility cost of acquiring drugs and biological products. As we explained in the proposed rule, 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 of this final rule, is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions.

We further noted that, 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/pdf-report/medicare-part-b-drugs->

[pricing-and-incentives](#)). In this brief ASPE notes several concerns with the ASP methodology. Two of those concerns relate to the economic incentives of cost and value. ASPE stated that the ASP methodology for Part B drugs falls short of providing value based incentives in several ways. Specifically, ASPE 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. ASPE noted that 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.

We also noted in the proposed rule that 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 discussed the meaning of the 6 percent that is added to the ASP and stated: “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, we stated in the CY 2019 ESRD PPS proposed rule that with regard to acquisition costs in a 2006 Report to Congress titled, “Sales of Drugs and Biological products 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, but was unable to obtain data on ASP by type of purchaser from the drug manufacturers, and was 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. We noted that 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 biological products to the majority of ESRD beneficiaries.

We explained in the proposed rule that 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 noted that 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 biological products. Therefore, we proposed 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).

We noted that this proposal would apply to new renal dialysis drugs and biological products that fall within an existing functional category and to those that do not fall within an existing functional category. We stated that we believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products 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 noted that we believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products 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 biological products. We noted 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 its June 2015 report, there is no consensus amongst stakeholders.

We further explained that we believe 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 biological products 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 final rule. That is, we proposed to provide the TDAPA for new drugs that are within an existing functional category, which is an expansion of the existing policy. We stated that 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 final rule. We solicited comment on the proposal to revise § 413.234(c) to reflect that we would base the TDAPA payments on ASP+0. While we proposed 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 also solicited 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.

We stated in the proposed rule that there are times when the ASP is not available. For example, when a new drug or biological product 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 proposed 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 solicited comment on this proposal.

We noted that this proposal to use ASP+0 as the basis for the TDAPA payments, if adopted, would apply prospectively to new drugs and biological products 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. We explained that this proposal would not affect calcimimetics, which would continue to be eligible for the TDAPA payment based on ASP+6.

The comments and our responses to the comments on the basis of payment for the TDAPA proposal are set forth below:

Comment: MedPAC commented that if CMS decides to finalize the proposed policy and apply TDAPA to new renal dialysis drugs that fit into an existing functional category, CMS

should not make duplicative payments for a new product (assigned to a functional category) by paying the TDAPA for 2 years and paying for its functional category under the ESRD PPS base rate. For example, the agency could reduce the TDAPA amount to reflect the amount already included in the base rate. In addition, CMS could consider paying a reduced percentage of the estimated incremental cost of the new drug as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices.

A drug manufacturer disagreed with MedPAC, pointing out that its product is an advance that substantially improves beneficiary outcomes and that CMS's assessment of the cost of other drugs in its functional category is trivial (the commenter asserted that there appears to be approximately 59 cents currently allocated in the ESRD PPS rate for the functional category). The manufacturer stated that the amount currently in the ESRD PPS rate does not account for the hundreds of millions of dollars it costs to develop a new, breakthrough drug; thus, a TDAPA would not be duplicative.

Response: We understand MedPAC's suggestion is to base the TDAPA payment amount on a value that takes into account the dollars already included in the ESRD PPS base rate for the functional category. While we did not propose this approach, we can consider this mechanism in the future. With regard to the commenter that disagreed with MedPAC's comment, we appreciate the concern and understand there could be new renal dialysis drugs and biological products that have a high cost which is not directly accounted for by the functional category. However, as we mentioned previously, we did not propose to change the determinant on how a new renal dialysis drug or biological product is considered reflected in the ESRD PPS base rate, therefore, in the situation described by the commenter, this new high cost drug would be considered reflected in the base rate since it falls within an existing functional category. The

ESRD PPS is a payment system that takes into account the resource use of the ESRD facility for furnishing renal dialysis services to Medicare beneficiaries. We will, however, consider this situation in the future.

Comment: Although MedPAC did not support the proposal to expand the TDAPA to all new dialysis drugs that fit into a functional category, MedPAC believed there was good rationale for CMS's proposal to change the basis for the TDAPA from ASP +6 percent to ASP with no percentage add-on. MedPAC pointed out that the ASP +6 percent policy was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. While the policy never stated what cost the "+6 percent" was intended to cover, MedPAC noted that applying the policy to dialysis facilities is considerably different from reimbursing physicians. First, the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for dialysis facilities. If the intent of the "+6 percent" was to address acquisition price variation, MedPAC believes that rationale is diminished for dialysis facilities. Second, MedPAC noted that the TDAPA is in addition to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. Therefore, if the intent of the "+6 percent" was to address storage and administration costs, MedPAC believes these costs are already addressed through the ESRD PPS bundled payment and do not contribute to the rationale for paying ASP +6 percent for the TDAPA. MedPAC stated that, overall, the proposal to change the basis of the TDAPA to ASP with no percentage add-on appears to be well founded.

Response: We appreciate MedPAC's support for this proposal and agree that ASP +0 is appropriate as the basis for the TDAPA, particularly in light of the administrative costs included

in the ESRD PPS bundled payment amount.

Comment: Some commenters referenced an analysis completed by an analytic organization, stating that if CMS were to finalize the 100 percent ASP policy for TDAPA, and that amount were used to fold drugs and biological products into the ESRD PPS, there will be insufficient dollars available to provide access to these products for patients. They stated that the actual payment amount would be closer to ASP-1.6 or lower.

Some commenters expressed concern that the ASP+0 proposal will result in a provider reimbursement falling far below that amount given: (1) the exclusion of the 20 percent coinsurance from bad debt recovery; (2) the fact that many states fail to fulfill their cost sharing obligations for dual-eligible beneficiaries; and (3) the budget sequestration. The commenter further explained that this considerable underpayment will challenge dialysis facilities' ability to offer a new drug or biological product during the TDAPA period.

Response: We appreciate all of the feedback we received from the commenters with regard to basing payment for TDAPA at ASP+0 as opposed to using the pricing methodologies available under section 1847A of the Act.

With regard to the concerns that ASP+0 will effectively yield a reimbursement below ASP after sequestration and bad debt reductions are applied, as discussed previously, the TDAPA policy is for purposes of the ESRD PPS and not designed to offset or mitigate other statutorily required cuts and instances in which facilities cannot recover beneficiary cost sharing.

The TDAPA is a payment adjustment under the ESRD PPS, and we continue to believe it is not intended to be a mechanism for payment for new drugs and biological products under Medicare Part B. We believe that we have flexibility to determine the basis for payment for TDAPA on a methodology outside of how Part B pays because we need to take into account

impacts to the Medicare Trust Fund when there are already administrative costs reflected in the ESRD PPS base rate. As a result we have reconsidered the use of pricing methodologies under section 1847A of the Act and proposed ASP+0, as discussed above in section II.B.1.f of this final rule. We agree with MedPAC that the ASP+6 percent policy was developed to reimburse physicians for the cost of drugs and that the TDAPA is in addition to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. Therefore, we believe basing the TDAPA payment on ASP+0 is appropriate and we are finalizing the proposal.

Comment: Some commenters explained that the ESRD PPS is unique and fragile and operates at razor-thin margins, with many facilities operating with negative Medicare margins. One commenter stated that it is not appropriate to assume that because a functional category exists there is sufficient funding for all future drugs and biological products developed to treat such conditions. One commenter expressed strong concern about the proposal and explained that facilities will have to reconcile potential differences in the amount that CMS reimburses in TDAPA and the amount that the facilities actually pay for new prescription drugs and associated costs of administering them to patients (overhead). The commenter stated that this discrepancy could have the unintended consequence of discouraging dialysis providers from including new therapies on their formularies.

Some commenters expressed concern regarding the impact the proposal would have on medium and small dialysis organizations. One commenter stated that payment at ASP+0 may create a disincentive for medium and small dialysis organizations to acquire the product and provide it in their facilities because they may be under-reimbursed. This could lead to patient access issues in obtaining the drug as clinicians may be hesitant to prescribe a new therapy if

they know the dialysis facilities are not stocking it.

Many commenters expressed concern that ASP+0 is not sufficient to cover the cost of administering the drug or biological product during the transition period. One commenter stated that it is inappropriate to assume that new drugs and biological products will have the same administrative and overhead cost profile, or that dialysis facilities can simply cover these costs for multiple drugs or biologics with the current dollars. Commenters explained that drugs and biological products require support for costs related to storage, management, delivery, packaging, administration, and dispensing. Further, the availability of novel drugs and biological products will necessitate the dedication of resources to develop clinical protocols, educate and train staff, and change medical record and billing systems. Another commenter explained that some dialysis providers face unique and significant costs associated with implementing the TDAPA, including setting up and paying for pharmacy systems and substantially updating internal billing systems to comply with the TDAPA regulations. The commenter also stated that fulfillment, distribution and waste costs paid to dispensing pharmacies, as well as billing and administrative costs for these providers are examples of unique costs that would be better addressed with an ASP+6 policy. Another commenter stated that some dialysis providers face additional hurdles, such as state pharmacy laws, which make more complex their ability to “dispense” medication. This commenter further explained that the consequence of adding new drugs, especially oral drugs, to the ESRD PPS is that an elaborate operational and clinical system is required when a new oral medication is approved and qualifies for the TDAPA in order to ensure patients receive the product and that dialysis providers can bill for the product. This commenter noted that these drugs were not included in the ESRD PPS at the outset or in the composite rate and therefore the administrative costs of developing the infrastructure to deliver

new pharmaceutical products, especially oral drugs, is not built into the ESRD PPS.

Another commenter explained that there are costs associated with establishing pilot programs, typically the manner in which dialysis organizations would evaluate the benefits and risks of newly approved therapies. This commenter further explained that pilot programs often involve chart reviews, selection of patients to initiate therapy, titration of dosing, additional lab monitoring, evaluation of outcomes, and ultimately incorporation into modified treatment protocols, if facilities determine there is value to the utilization of a new therapy. This would occur after a thorough evidence review of registration trials, peer reviewed literature and other clinical outcomes data.

Some commenters noted that setting the TDAPA at ASP+0 will not likely have any impact on the drug or biological product's price. One commenter explained that there are challenges of delivering care with limited resources when the cost of prescription pharmaceuticals is outside of its control and frequently on the rise. The commenter expressed concern that none of the systemic issues that the Administration seeks to address regarding pharmaceutical prices will be changed by reducing the payment rate for drugs and biological products in the ESRD PPS from ASP+6 to ASP+0 because this change does not affect the actual price of pharmaceuticals. Instead, it only affects what Medicare will reimburse providers for the price they still have to pay to pharmaceutical companies. The commenter indicated that this reduction have a negative impact on dialysis facilities and further limit their ability to provide quality care to Medicare beneficiaries.

Some commenters explained that ASP is driven by the "average" sales price for a drug to all purchasers, including hospitals and large purchasing groups, net of all manufacturer rebates, discount, and price concessions. A few commenters noted that while the drugs and biological

products contained within the ESRD PPS are required to be “renal dialysis services” that are “furnished for the treatment of ESRD,” it is not necessarily the case that dialysis facilities are the only – or largest – purchasers of the drugs and biological products in question. The commenters asserted that it is therefore faulty logic to assume that dialysis providers are necessarily the entities whose purchase price is represented by ASP. Commenters stated that many dialysis facilities are unable to acquire some drugs and biological products at or below ASP and may find that even ASP+6 does not adequately cover their costs to acquire and deliver drugs to beneficiaries.

Another commenter stated that many dialysis facilities may not have the leverage or capacity to purchase the drug or biological product at or below the ASP, for example, small ESRD facilities and ESRD facilities in rural areas do not have the buying power of large dialysis organizations. The commenter further explained that for these facilities, the cost to provide drugs and biological products is higher than the average and includes additional costs such as transportation to the rural area. Often a drug is shipped to a central location and then transported to rural facilities which adds both transportation and administrative costs. Another commenter noted that drug manufacturers do not give small and mid-sized facilities the same discounts received by the two largest dialysis providers.

Response: With regard to the concerns that ASP+0 will not cover the administrative costs associated with bringing a new drug or biological product as a therapeutic option in a facility, we point out that under the current ESRD PPS, new renal dialysis drugs that are considered to be in a functional category do not receive any additional payment. Payment for these drugs has been included in the ESRD PPS bundled payment amount since the inception of the ESRD PPS. We note that with this new policy, effective January 1, 2020, ESRD facilities

will now get a payment adjustment for 2 years for new renal dialysis drugs and biological products, whereas before they did not. We continue to believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products 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. Beyond just capturing administrative costs in the base rate, there are also payment dollars for the respective functional category included in the base rate which, we believe, mitigates the financial risk to the facilities.

We are concerned with the comment regarding that the discrepancy between ASP+0 and ASP+6 could have an unintended consequence of discouraging dialysis providers from including new therapies on their formularies. Under the ESRD PPS, ESRD facilities are responsible for furnishing all renal dialysis services directly or under arrangement. We understand that small, medium, and rural facilities may have additional challenges related to acquisition costs, transportation, and delivery which could lead to inequitable access for beneficiaries served by those communities. Again, we note that currently new renal dialysis drugs have entered the market since the implementation of the ESRD PPS in 2011 and were immediately rolled into the bundled payment rate. We believe the same would be true for new drugs and biological products and we believe the dollars included in the base rate for the specific functional groups would mitigate these challenges. Effective January 1, 2020, ESRD facilities will now get a payment adjustment for 2 years for new renal dialysis drugs and biological products, whereas before they did not.

With regard to pilot programs, we believe the issues that were mentioned are addressed by FDA clinical trials for new drug applications. For generic drugs, part of the reason they are approved in the section 505(j) program is that these safety and drug response issues have been

addressed. It would seem that what the commenter is asking us to pay for is an evaluative business model and that is not considered payment for the treatment of a medical condition.

With regard to the comment asserting that the consequence of adding new drugs, especially oral drugs, to the ESRD PPS is that an elaborate operational and clinical system is required when a new oral medication is approved and qualifies for the TDAPA in order to ensure patients receive the product and that dialysis providers can bill for the product, we believe this issue should be mitigated with the 1-year delay finalized in section II.B.1.e of this final rule. We note that there are oral equivalent drugs that have been bundled in the ESRD PPS since its inception.

Comment: One commenter noted that patient's out-of-pocket costs may be higher with an ASP+6 TDAPA than under the ASP+0 proposal, however the commenter believed the trade-off of spurring innovation in new treatments warrants the cost. The commenter stated that while it would prefer that the coinsurance would not be applied to TDAPA given this is a facility-level adjuster to the PPS, they recognize that CMS has stated it does not have the authority to waive the coinsurance.

Response: We do not agree with the commenter that the TDAPA is a facility-level adjustment to the ESRD PPS. The TDAPA is a patient-level adjustment because it is only applicable if the patient is furnished the drug or biological product. We appreciate that coinsurance is a concern, but as the commenter noted, we do not have the authority to waive coinsurance requirements.

Comment: While some commenters appreciated CMS working to reduce drug pricing, they expressed concern that changing the basis of payment for the TDAPA from ASP+6 to ASP+0 will not encourage innovation despite CMS's intent. Commenters stated that there has

been little innovation in new ESRD therapies in over 2 decades and they requested that CMS not apply this untested new pricing policy to the TDAPA under the ESRD PPS.

Several commenters discussed the Kidney Accelerator (KidneyX) project. The commenters noted that the Department of Health and Human Services (HHS) indicated that the project “sends an important message to investors and innovators regarding the desire and demand for new therapies.” Commenters explained that in addition to the activities around KidneyX, CMS needs to make sure that its policies also promote innovation and advances in case across these stakeholder groups and that properly aligning the payment component is essential to advancing innovation as well. The commenters stated that the ASP+0 proposal could result in creating a disincentive for the adoption and development of new drugs and biological products and undermines the KidneyX initiative. The commenters explained that promoting innovation in kidney care requires taking into account patients, providers, and manufacturers and that CMS should provide ASP +6 percent via TDAPA so that the cost of evaluation, training and implementation is cost-neutral and providers will be eager to evaluate and utilize new therapies, and innovation of new products will be spurred in the renal space.

Response: We agree with commenters that innovation and the KidneyX project are important and necessary for the development of new therapies. We believe that basing the TDAPA at ASP+0 provides sufficient resources to incentivize the development of new, innovative therapies and is a supplement to the KidneyX project. We believe that ASP+0 is sufficient because the ESRD PPS provides on a per treatment basis payment for administrative activities, including packaging and handling of drugs and staff costs. This per treatment payment along with the TDAPA is a reasonable basis for payment because we believe it mitigates the financial risk to the ESRD facilities. One of the objectives of KidneyX is to bring to market not

only medications that will slow the progression and/or reverse kidney disease, but also drugs and biological products that will cure kidney disease. We believe providing the TDAPA for all new renal dialysis drugs and biological products provides an incentive for innovation as part of the treatment pathway for mitigating, reversing and ultimately curing ESRD.

Comment: A few commenters referred to CMS' experience in the hospital outpatient setting when it tried to shift to ASP+4 percent. The commenter asserted that between 2009 and 2012, CMS worked to establish the appropriate payment rate for separately paid drugs in the hospital outpatient setting. During this time, CMS made various shifts in the percentage added to the ASP, but eventually for CY 2013 concluded that the only way to establish a predictable and accurate payment for these drugs that recognized the real overhead costs associated with providing them was to set the amount at ASP+6 percent. The commenter noted that none of the proposals in the outpatient setting over the years ever suggested setting the rate at 100 percent of ASP. Some commenters suggested that the basis of payment policy remain consistent with how Medicare Part B pays other provider settings, for example, Physician Fee Schedule and the hospital outpatient PPS.

Response: Again, we believe that ASP+0 is sufficient because the ESRD PPS provides on a per treatment basis payment for administrative activities, including packaging and handling of drugs and staff costs. This payment along with the TDAPA is a reasonable basis for payment because we believe it mitigates the financial risk to the ESRD facilities. We appreciate the comments on the Medicare payment adjustments for the hospital outpatient setting and physician offices. MedPAC, which agreed with us, noted that the TDAPA is in addition to the ESRD PPS base rate, which already includes payment for the cost of storage and administration of renal dialysis services, therefore if the intent of the 6 percent is to address storage and administration

costs, additional payment is not necessary. The ESRD PPS per treatment payment amount is paid for every dialysis treatment regardless of the items and services furnished. We will monitor the efficacy of payment for the ESRD PPS under TDAPA.

Comment: We received two comments on the proposal that in the event ASP is unavailable for a drug, WAC+0 would be used, and in the event both ASP and WAC are unavailable, the manufacturer's invoice would be used as the basis for the TDAPA payment. The commenters did not support WAC+0, and one commenter recommended that we base the payment in this circumstance on WAC+6. The other commenter suggested that, for instances in which ASP is not available, CMS should base payment on WAC+3 to be consistent with the hospital outpatient department. Both commenters supported basing the TDAPA on the manufacturer's invoice in the event ASP and WAC are not available.

Response: We appreciate the comments on our proposal for situations when ASP is unavailable. However, we believe that this is the same rationale that we discuss above. We believe that the administrative costs of packaging, handling, and staff are included in the ESRD PPS base rate and therefore the TDAPA is a reasonable basis for payment because we believe it mitigates the financial risk to the ESRD facilities. With regard to the consistency with other payment systems, we believe that they have different administrative circumstances. We appreciate that the commenters supported use of the manufacturer's invoice in the event ASP and WAC are not available.

Comment: Two commenters expressed concern that while the preamble of the proposed rule stated that the proposed drug designation changes would not apply to the use of ASP+6 percent for calcimimetics, the regulatory text is not clear. Commenters supported the statement in the preamble that CMS has not changed the TDAPA policy for calcimimetics with the new

drug designation policy and strongly supports maintaining the policy as it is today. However the commenter is concerned that this intent be reflected in the regulatory text as well.

Response: We appreciate the feedback on the ambiguity of the regulatory text. We are finalizing a revision to the drug designation process regulations to reflect that for calcimimetics, the basis of payment will be based on pricing methodologies under section 1847A of the Social Security Act (which includes ASP+6). We are maintaining the current policy for calcimimetics because these drugs are the only ones that qualify for the TDAPA at this time and are currently receiving the adjustment, and the basis of payment was established when they were launched. We note that any new injectable or intravenous product that is eligible for TDAPA until January 1, 2020 would be paid under the current policy, which is a TDAPA based on pricing methodologies under 1847A of the Act (which include ASP+6). As of January 1, 2020, all new renal dialysis drugs and biological products, regardless of functional category status, will be paid the TDAPA based on ASP+0.

Final Rule Action: After considering the public comments, we are finalizing the policy as proposed with two revisions. Specifically, we are finalizing the revision of § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we base the TDAPA payments on ASP+0 instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6), effective January 1, 2020. Since there are times when ASP is not available, we are finalizing that the TDAPA payment is based on WAC+0 and, when WAC is not available, the TDAPA payment is based on the drug manufacturer's invoice, effective January 1, 2020. We are also finalizing a revision to the proposed § 413.234(c) to reflect that the basis of payment for TDAPA for calcimimetics continues to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6).

h. Drug Designation Process for Composite Rate Drugs and Biological Products

In the CY 2016 ESRD PPS final rule, we did not discuss composite rate drugs and biological products 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 product 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, antiarrhythmics, 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, under § 413.237, composite rate drugs and biological products are not permitted to be considered for an outlier payment. The outlier policy is discussed in section II.B.3.c of this final rule.

Composite rate drugs and biological products 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 biological products 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, is not included under the ESRD PPS.

In light of our proposal to expand the drug designation process and the TDAPA, we also proposed, under the authority of section 1881(b)(14)(D)(iv) of the Act, that it extend to composite rate drugs and biological products that are furnished for the treatment of ESRD. Specifically, we proposed that beginning January 1, 2019, if a new renal dialysis drug or biological product as defined in the proposed revision at § 413.234(a) is considered to be a composite rate drug or biological product and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. We noted that composite rate drugs and biological products 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 stated in the proposed rule that we believed 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 proposed that the expanded drug designation process and the TDAPA policy we proposed in section II.B.1.f of this final 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 did not propose to change the current outlier policy under § 413.237, which does not apply to composite rate drugs. We did, however, solicit 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 final rule).

We solicited comment on the proposal to recognize composite rate drugs and biological products 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.

The comments and our responses to the comments on our proposal to extend the TDAPA expansion proposals to composite rate drugs and biological products that are furnished for the treatment of ESRD are set forth below.

Comment: MedPAC commented that we should not proceed with our proposal to apply the TDAPA policy to new renal dialysis drugs that would be considered composite rate drugs for the same reasons that MedPAC believes we should not proceed with our proposal to apply the TDAPA to new renal dialysis drugs that would fall into an existing functional category.

Some commenters referred to the inclusion of composite rate drugs in their overall comments regarding the TDAPA expansion and supported their inclusion in the drug designation process.

Response: We appreciate MedPAC's feedback on our proposal to apply the TDAPA to composite rate drugs. As we stated in section B.1.f of this final rule, we believe that allowing all new renal dialysis drugs and biological products to be eligible for TDAPA will provide an ability for a new drug to compete with other similar drugs in the market which could mean lower prices

for all drugs. We believe that new renal dialysis composite rate drugs could benefit from this policy as well. Additionally, we continue to 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. We will continue to monitor the use of the TDAPA, carefully evaluate the new renal dialysis drugs and biological products that qualify, and address any concerns through future refinements to the TDAPA policy.

Final Rule Action: After the consideration of public comments, we are finalizing our policy to extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. Specifically, beginning January 1, 2020, if a new renal dialysis drug or biological product as defined in the proposed revision at § 413.234(a) is considered to be a composite rate drug or biological product and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. We note that composite rate drugs and biological products will not be eligible for an outlier payment after the TDAPA period.

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 in furnishing such services. We have established a 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” mean 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 in § 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

As we discussed in the CY 2019 ESRD PPS proposed rule, 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 that new Medicare provider billing numbers qualify for the LVPA, which takes 3 years. We have also discovered that facilities that change their fiscal year without going through a CHOW become ineligible for the adjustment. Finally, stakeholders have recommended 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 its payments are significantly reduced. Thus, in order to be responsive to stakeholders and increase flexibility with regard to eligibility for the LVPA, we proposed to make changes to the LVPA regulation at § 413.232.

The first proposed revision concerned the assignment of a PTAN when a facility undergoes a CHOW as described in 42 CFR 489.18. Under § 413.232(b)(2) and (g)(2), a facility

is ineligible 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 believed that the 3-year timeframe provided us with a sufficient span of time to view consistency in business operations.

However, as we noted above and in the CY 2019 ESRD PPS proposed rule, we have heard from stakeholders that this policy unfairly affects 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.

As we stated in the CY 2019 ESRD PPS proposed rule, 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. We noted that 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, the facility should continue to be eligible for the LVPA since this indicates a consistency in business operations.

We proposed 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. We noted that this proposal does not extend to CHOWs where a new PTAN is issued for any other reason. We solicited 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 also proposed 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 solicited comment on this proposal.

We also proposed to allow for an extraordinary circumstance exception to the November 1 attestation deadline under § 413.232(e). As we explained in the CY 2019 ESRD PPS proposed rule, 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

noted that we expect extraordinary exceptions to be rare and the determination of acceptability would be made on a case-by-case basis. We stated that 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 proposed 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 proposed that the facility would need to submit a narrative explaining the rationale for the exception to their MAC. We stated that 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 solicited 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 proposed 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 stated in the CY 2019 ESRD PPS proposed rule that we recognize 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 noted that we did not intend for an ESRD facility to lose its LVPA eligibility simply because the facility made a decision to change its cost reporting period. The requirement that cost reports span 12-consecutive months was to bring a measure of consistent business operations.

We proposed 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 proposed 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. We stated that this proposal would not impact or change requirements for reporting, as established by the MACs, or those set forth in § 413.24(f)(3). We solicited comment on the proposal to add § 413.232(g)(3) to change the information and cost report timeframes MACs would review to determine LVPA eligibility. We noted that this provision 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 facilities to continue to receive the adjustment.

Finally, we proposed 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)”. We explained that 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 would clarify that the reference to miles in § 413.232(c)(2) is to

road miles. We noted that CMS recognizes the current designation of miles under the regulation may not be specific enough and could cause confusion, and we have issued guidance in the Medicare Benefit Policy Manual (Pub. L. 100-02), Chapter 11, Section 60, addressing road miles. Accordingly, we proposed clarifying edits to § 413.232(c)(2).

We did not receive comments regarding the two technical corrections to the regulations text for the LVPA or the proposed extraordinary circumstances exception; therefore, we are finalizing these revisions as proposed.

The comments and our responses to the comments on our other proposed revisions to the LVPA requirements and regulations are set forth below.

Comment: Several commenters supported the proposed revisions to the LVPA regulations. A large dialysis organization (LDO), a health plan, a dialysis organization and a dialysis provider organization expressed support for CMS' proposals to allow ESRD facilities to continue to receive LVPAs when there are changes that do not affect the business operations of the facility. Specifically, they stated that they support and appreciate CMS' proposed policies to allow facilities to retain low-volume facility status when a new owner accepts assignment of the existing Medicare provider agreement and when a facility changes its fiscal year-end for cost reporting purposes.

A patient advocacy organization commented that as CMS is proposing changes to the LVPA, CMS should consider removing the rural payment adjuster and instead include tiers for the LVPA to ensure it applies the most dollars to facilities that are serving a critical patient need and likely operating at a loss. The organization remains concerned that facilities in isolated areas serving predominately Medicare and Medicaid beneficiaries would be the first to be targeted for closure even with a rural payment adjuster. The

organization pointed to the March 2018 MedPAC report that distinguished rural facilities adjacent to an urban area from rural non-adjacent facilities and stated that CMS should implement a tiered approach to the LVPA and ensure those facilities not adjacent to an urban area are receiving a higher adjuster.

Response: We appreciate the stakeholders' support for the LVPA proposals. With regard to the implementation of tiered LVPA adjustment, this comment is out of scope for this rule because we did not propose any changes to the structure of the LVPA adjustment or the rural adjustment, however, we will consider this recommendation for future refinements to those policies. Additionally, we are undertaking a new research effort and plan to engage with stakeholders further on this issue.

Final Rule Action: After considering the comments, we are finalizing the revisions to the LVPA regulations as proposed, with one technical edit. We are finalizing the revision to § 413.232(b)(2) to expand the definition of a low-volume facility 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 definition does not extend to CHOWs where a new PTAN is issued for any other reason. We are also finalizing the amendment of § 413.232(g)(2) to recognize the expansion of the low-volume facility definition and allow for PTAN changes when the facility type changes as a result of a CHOW.

In addition, we are finalizing the revisions to § 413.232(e) to include an exception to the attestation deadline of November 1st for extraordinary circumstances. In order to request an extraordinary circumstance exception, the facility will need to submit a narrative explaining the rationale for the exception to its MAC. The MAC will evaluate the narrative

to determine if an exception is justified, and such a determination will be final, with no appeal.

Additionally, we are finalizing the addition of 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. MACs should 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 policy does not impact or change any other requirements for cost reporting, as established by the MACs, or those set forth in § 413.24(f)(3). This policy applies 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. We are making one technical change to refer to an ESRD facility that has changed “its” cost reporting period.

Finally, we are finalizing two technical corrections to the LVPA regulations. We are finalizing the revision to § 413.232(b) to reflect the correct cross-reference by changing “paragraph (h)” to “paragraph (g)” and the revision to § 413.232(c)(2) to reflect road miles.

3. Final CY 2019 ESRD PPS Update

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

i. 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 proposed 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 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 proposed to use CY 2016 as the base year for the rebased ESRDB market basket cost weights. The cost weights for the 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 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 proposed 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 "rebasings" and "revising," while often used interchangeably, actually denote different activities. The term "rebasings" means moving the base year for the structure of costs of an input price index (that is, in the CY 2018 proposed rule (83 FR 34318), we proposed 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 proposed to rebase the ESRDB market basket to reflect the 2016 cost structure of ESRD facilities. For CY 2019, we did not propose to revise the index; that is, we did not propose 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 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 proposed 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 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 proposed 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 market basket. This is similar to the methodology we used to break the Administrative and General cost weight into more detail for the 2012-based ESRDB market basket (79 FR 40217 through 40221). The only difference is that for this 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 proposed to include a total of 20 detailed cost categories for the 2016-based ESRDB market basket, which is the same number of cost categories as the 2012-based ESRDB market basket. We proposed 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 labor-related share.

The comments and our response to the comments on our proposal to rebase the ESRDB market basket are set forth below.

Comment: Several commenters supported the rebasing of the ESRDB market basket to a 2016 base year.

Response: We appreciate the commenters' support.

A more thorough discussion of the market basket 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, values less than the 5th percentile or greater

than the 95th percentile were excluded from the major cost weight computations. The 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 final 2016-based ESRDB market basket and 2012-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 2: 2016-based ESRDB Market Basket Major Cost Weights Derived from the Medicare Cost Report Data

Cost Category	2016-based ESRDB Market Basket	2012-based ESRDB Market Basket
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 proposed 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 calculated to yield the 2016 ESRDB market basket expenditure categories and weights.

Wages and Salaries

The 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 were 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 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 percentages 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 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 proposed 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 proposed 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 cost weight for Wages and Salaries increases to 34.5 percent when contract labor wages are added. The calculation of the 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: 2016 and 2012 ESRD Wages and Salaries Cost Weight Determination

Components	2016 Cost Weight	2012 Cost Weight	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 PPS proposed rule (79 FR 40218) to the 2016-based Benefits cost share derivation.

TABLE 4: 2016 and 2012 ESRD Employee Benefits Cost Weight Determination

Components	2016 Cost Weight	2012 Cost Weight	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 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 proposed 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 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 an ESRDB market basket weight for Pharmaceuticals of 12.4 percent. ESA expenditures accounted for 10.0 percentage points of the 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 ESRDB market basket to the 2016-based ESRDB 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 had an effect on the overall Pharmaceutical cost weight in the 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 proposed to include this provider's decline in our market basket results treating it as a 'real' change in relative pharmaceutical costs. We did not propose to use an alternative methodology, such as averaging cost weights from multiple years, which we proposed for Lab Services as stated below.

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 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 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 through 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)

Report². Because the recent reported costs from this chain reflect these unique circumstances, we proposed 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 (1.5 vs 2.2 percent) from the 2012-based ESRDB market basket to the 2016-based ESRDB 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 2016-based ESRDB market basket weight for Housekeeping and Operations of 3.9 percent.

Capital

We developed a 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

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>

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 and 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 2016-based ESRDB market basket weights for Capital-related Buildings and Fixtures and Capital-related Machinery are 9.2 percent 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 removed contract labor from this cost category and apportioned 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 further disaggregated 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 repeated this practice for each year to 2016. We then calculated 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 2016-based ESRDB 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 2016-based ESRDB market basket compared to the 2012-based ESRDB market basket.

TABLE 5: Comparison of the 2016-based and the 2012-based ESRDB Market Basket Cost Categories and Weights

2016 Cost Category	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

2016 Cost Category	2016 Cost Weights (percent)	2012 Cost Weights (percent)
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.

The comments and our response to the comments on the proposed cost category weights are set forth below.

Comment: One commenter had a question related to the methodology for estimating the cost weight for the pharmaceuticals and lab services in the proposed ESRDB market basket rebasing. The commenter noted that, per the proposed rule, the pharmaceuticals and lab services cost categories are influenced significantly by one LDO. The commenter questioned the rationale of CMS’s proposal to smooth the change in the lab services cost weight while, at the same time, not proposing to smooth the change in the pharmaceutical cost weight. The commenter stated that this difference in treatment seems inconsistent and recommended that CMS consider using a similar “smoothing” approach for both the pharmaceuticals cost weight and the lab services cost weight. The commenter further stated that, CMS has used phase-ins and smoothing methods when there were significant changes in the past.

Response: We did not propose to use a “smoothing” or averaging approach for the proposed 2016-based pharmaceutical cost share weight because the decline in pharmaceutical costs, relative to the other cost categories, were based on a steady pattern of falling pharmaceutical expense shares from 2012 to 2016 for all ESRD providers. In the CY 2019 ESRD PPS proposed rule (83 FR 34321), we noted that one provider experienced a relatively larger drop in its pharmaceutical cost weight relative to other providers. This LDO would have

renegotiated its agreement on the prices for ESA's in 2016 since the agreement between the LDO and a major drug manufacturer ended in 2015. This renegotiation should have contributed to the large drop in the LDO's pharmaceutical cost weight.

On the other hand, the rationale for using a 2-year average to determine the 2016 cost share weight for lab services was based on the documented instance of an LDO provider overbilling for lab services. The resulting low weight reported in 2016 was not reflective of normal business operations but was instead indicative of a correction to laboratory expenses. Therefore, reported laboratory expenses for 2013, 2014, and 2015 were higher than they should have been and laboratory expenses for 2016 were lower than they should have been since the LDO was required to reimburse Medicare for the prior overbilling. Given these unique circumstances, we proposed to average the lab cost weights for 2015 and 2016 for this chain. We did not average the lab cost weight for any other providers. This particular situation is documented in detail in the January 2016 Health and Human Services Office of the Inspector General (OIG) Report and was referenced in the proposed rule (83 FR 34322).

We did provide a rationale for the difference in the way we are estimating both the pharmaceuticals and lab services cost weight in the proposed rule, where we noted the OIG report and our analysis and research of the pharmaceutical cost weight trends. Thus, we disagree with the commenter that we should use a phase in or smoothing method for the pharmaceutical cost share weight for the 2016-based ESRDB market basket, as we believe the 2016 pharmaceutical cost weight reflects the pharmaceutical expenses experienced by providers in 2016. In contrast, we believe the lab services cost weight was being influenced by a reporting issue for one provider and did not reflect industry trends for 2016; therefore, averaging reported

expenses for this provider produces a cost weight for 2016 that more appropriately reflects these industry trends.

After consideration of public comments, we are finalizing the 2016-based ESRDB market basket cost categories and weights as proposed without change.

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

After developing the cost weights for the 2016-based ESRDB market basket, we select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based the 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 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 2016-based ESRDB market basket. We note that we proposed 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 proposed to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the 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 Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) 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 Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). 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 Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). 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 Wages and Salaries

We proposed using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). 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 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: ECI Blend for Wages and Salaries in the 2016-Based and 2012-Based ESRDB Market Baskets

Cost Category	ECI Series	2016 Weight	2012 Weight
Health Related Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Hospitals	79.9%	79.0%
Management Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial	6.7%	8.0%
Administrative Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support	7.7%	7.0%
Services Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Service Occupations	5.7%	6.0%

Employee Benefits

We proposed to continue using an ECI blend for Employee Benefits in the 2016-based ESRDB market basket where the components match those of the Wage and Salaries ECI blend. The occupation weights for the blended Benefits price proxy are the same as those 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 Benefits

We proposed 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 #CIU1016220000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS.

Management Benefits

We proposed 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.

Administrative Benefits

We proposed 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.

Services Benefits

We proposed 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 the 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 benefits ECI blend.

TABLE 7: ECI Blend for Benefits in the 2016-Based and 2012-Based ESRDB Market

Baskets

Cost Category	ECI Series	2016 Weight	2012 Weight
Health Related Benefits	ECI for Benefits for All Civilian Workers in Hospitals.	79.9%	79.0%
Management Benefits	ECI for Benefits for Private Industry Workers in Management, Business, and Financial.	6.7%	8.0%
Administrative Benefits	ECI for Benefits for Private Industry Workers in Office and Administrative Support.	7.7%	7.0%
Services Benefits	ECI for Benefits for Private Industry Workers in Service Occupations.	5.7%	6.0%

Electricity

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 as it reflects vitamins and nutrients. 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 proposed 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 proposed 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 proposed 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

In the proposed rule, we stated that we would continue using the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category (83 FR 34325). This series name and series code from the proposed rule were incorrect. The series that we use to proxy the Housekeeping and Operations cost category is the PPI Industry for Janitorial Services (BLS series code #PCU561720561720). This is the same price proxy that was used in the 2012-based ESRDB market basket and is the same price proxy that we proposed to use in the 2016-based ESRDB market basket. Therefore, we have a technical correction to the price proxy for Housekeeping and Operations. Specifically, we will continue using the PPI Industry for Janitorial Services for this cost category, we incorrectly listed the series name as the PPI Commodity for Cleaning and Building Maintenance Services. This was not a proposed change to the price proxy for this category. We further note that the growth in these two indexes are essentially the same with an average growth rate of 1.4 percent over the 2010 through 2017 time period.

Professional Fees

We proposed 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 proposed 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 proposed 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 proposed 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 price proxies and cost weights for the 2016-based ESRDB Market Basket.

TABLE 8: Price Proxies and associated Cost Weights for the 2016-based ESRDB Market Basket

Cost Category	Price Proxy	2016 Cost Weight
Total ESRDB Market Basket		100.0
Compensation		43.6
Wages and Salaries		34.5
Health-related Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	27.6
Management Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	2.3
Administrative Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	2.7
Services Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	2.0
Employee Benefits		9.1

Cost Category	Price Proxy	2016 Cost Weight
Health-related Benefits	ECI for Total Benefits for All Civilian workers in Hospitals.	7.3
Management Benefits	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.6
Administrative Benefits	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.7
Services Benefits	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 - Industry - Janitorial 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.

The comments and our responses to the comments on our proposed price proxies are set forth below.

Comment: Several commenters recommended that CMS identify a more suitable price proxy to update non-ESA drugs. The commenters stated that they believe that the current proxy (PPI Commodity data for Vitamin, nutrient, and hematinic preparations) does not appropriately capture the price of drugs that fall within the non-ESA cost category. Specifically, the

commenters stated that Vitamin D analogs in this category, such as Doxercalciferol and Paricalcitol, are distinct from over-the-counter vitamins. They further assert that the non-ESA drugs in the bundle are unique chemical entities, Food and Drug Administration (FDA)-approved, and available by prescription only.

These commenters suggested the use of the BLS series PPI Commodity data for Chemical and allied products – Drugs and Pharmaceuticals, seasonally adjusted (series ID WPS063) because it is based on prescription drugs and would include fewer over-the-counter drugs.

Some commenters also noted that while the non-ESA drugs represent a small portion of overall cost of providing dialysis services currently, the proposed expansion of the transitional drug add-on payment adjustment (TDAPA) for all new renal dialysis drugs will likely result in a shift in the type and use of drugs (that is, the drug mix) that is included within the ESRD PPS bundled payment and introduce new oral products that deserve an accurate price proxy for updating.

Response: We finalized the use of a blended price proxy for the pharmaceutical cost category in the CY 2015 ESRD final rule (79 FR 66135). We proxied the ESA drugs in the 2012-based ESRDB market basket by the PPI for biological products, human use (PPI BPHU) and the non-ESA drugs in the market basket by the PPI for Vitamin, Nutrient, and Hematinic preparations (PPI VNHP).

We continue to believe that the PPI VNHP is the most technically appropriate price proxy for non-ESA drugs in the ESRDB market basket for several reasons. The non-ESA drugs included in the bundled per treatment amount are comprised primarily of vitamins and nutrients. While the PPI VNHP index does include over-the-counter drugs, it also includes prescription-

required vitamins and nutrients. The commenters' suggested index – the PPI for Drugs and Pharmaceuticals – mostly reflects drugs that are not reimbursable under the ESRD PPS. Furthermore, prescription-required vitamins and nutrients (such as non-ESA drugs included in the ESRD bundled payment) would represent a small proportion of drugs represented in this index, making it less representative of the non-ESA drug prices. Furthermore, analysis of the ASP data over the period 2012 through 2017 found the prices of the non-ESA drugs in the ESRD PPS bundle declined by 27.4 percent compared to the PPI VNHP which grew by 13.0 percent and the PPI for Drugs and Pharmaceuticals which increased by 34.5 percent.

The non-ESA drugs represent 2.4 percent of total costs in the 2016-based ESRDB market basket or 19 percent of all ESRD drug expenses for 2016. In comparison, non-ESA drugs represented 3.6 percent of total costs in the 2012-based ESRDB market basket, or 22 percent of all drug costs. This indicates that from 2012 to 2016, the relative costs (reflecting both price and quantity) faced by ESRD facilities for non-ESA drugs has grown slower than other ESRD costs included in the PPS ESRD bundle.

Lastly, we disagree with the commenters' rationale that we should switch to an alternative price index in anticipation of potential shifts in the mix of drugs within the ESRD PPS bundled payment amount as a result of the proposed TDAPA provisions. Any impact that would result from the proposed TDAPA expansion are unknown at this time. We will continue to monitor the impact that these changes have on the relative cost share weights in the ESRDB market basket, over time, as reported on the MCR data. When appropriate we will rebase the ESRDB market basket to reflect observed shifts in cost weights.

For the reasons stated above, we continue to believe it is technically appropriate to proxy the price change for non-ESA related drugs included in the ESRD PPS bundled payment by the

PPI VNHP. Therefore, we are finalizing the PPI VNHP as the price proxy for non-ESA drugs in the 2016-based ESRDB market basket.

After consideration of public comments, we are finalizing the price proxies of the 2016-based ESRDB market basket as proposed – noting the error in the CY 2019 ESRD PPS proposed rule for the Housekeeping and Operations cost category.

ii. CY 2019 ESRDB 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 proposed to use the 2016-based ESRDB market basket 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’s) 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

After consideration of public comments, we are finalizing the proposed 2016-based ESRDB market basket without modification. A comparison of the yearly changes from CY 2014 to CY 2021 for the 2012-based ESRDB market basket and the final 2016-based ESRDB market basket is shown in Table 9.

TABLE 9: Comparison of the 2012-based ESRDB Market Basket and the Final 2016-based ESRDB Market Basket, Percent Change, 2014-2021

	ESRDB Market Basket, 2012-Based	ESRDB Market Basket, 2016-Based	Difference (2016-Based less 2012-Based)
Historical data:			
CY 2014	1.6	1.5	-0.1
CY 2015	2.2	2.0	-0.2

	ESRDB Market Basket, 2012-Based	ESRDB Market Basket, 2016-Based	Difference (2016-Based less 2012-Based)
CY 2016	2.0	1.9	-0.1
CY 2017	1.3	1.4	0.1
Average CYs 2014-2017	1.8	1.7	-0.1
Forecast:			
CY 2018	1.7	1.7	0.0
CY 2019	2.2	2.1	-0.1
CY 2020	2.4	2.4	0.0
CY 2021	2.5	2.4	-0.1
Average CYs 2018-2021	2.2	2.2	0.0

Source: IHS Global Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018.

Table 9 shows that the forecasted rate of growth for CY 2019 for the 2016-based ESRDB market basket is 2.1 percent, which is 0.1 percentage point lower than the rate of growth as estimated using the 2012-based ESRDB market basket. The lower update is mainly due to a lower relative pharmaceuticals (particularly ESAs) cost weight in the 2016-based ESRD market basket compared to the 2012-based ESRDB market basket,

The growth rates in Table 9 are based on IHS Global Inc.'s (IGI) 3rd quarter 2018 forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. We noted in the proposed rule that if more recent data were subsequently available (for example, a more recent estimate of the market basket), we would use such data to determine the market basket increases in the final rule. In the proposed rule the forecasted rate of growth for CY 2019, based on IGI's 1st quarter 2018 forecast, for the 2016-based ESRDB market basket was 2.2 percent (83 FR 34326).

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 did not propose any changes to the methodology for the projection of the MFP adjustment.

Based on IGI's 3rd quarter 2018 forecast with history through the 2nd quarter of 2018, the projected MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2019) for CY 2019 is 0.8 percent.

We noted in the proposed rule that if more recent data were subsequently available (for example, a more recent estimate of the MFP adjustment), we would use such data to determine the MFP adjustment in the final rule. For comparison purposes, the proposed MFP adjustment for CY 2019 was 0.7 percent (83 FR 34327), and was based on IGI's 1st quarter 2018 forecast.

The comments and our responses to the comments on the proposed MFP adjustment for CY 2019 are set forth below.

Comment: Many commenters expressed their objection to the MFP adjustment to the ESRD PPS bundled payment update. Several commenters requested that CMS support development and adoption of a dialysis facility-specific productivity adjustment that: (1) better reflects factors that affect opportunities for productivity gains over which dialysis providers have little, if any, control; and (2) account for the statutory reductions to the ESRD PPS already in place to account for expected gains in efficiency.

The commenters provided several reasons why they believe that a MFP adjustment is not appropriate to apply to ESRD care which includes: overall rising labor costs, dialysis facilities

compliance with staffing minimums to assure quality of care, the mix of contracted and staffed employment, increased labor costs due to wage pressures, and additional administrative costs to comply with quality incentive program (QIP) reporting requirements.

One commenter noted that 55 percent of facilities have negative margins (as calculated by the Moran Company). The commenter also stated that MedPAC estimated ESRD margins at 0.5 percent. The commenter stated that these low margins challenge the idea that productivity can be improved year over year. One commenter further stated that the industry's ability to remain viable is directly tied to the unique private-public partnership that supports the Medicare ESRD program.

The commenters noted that current law requires CMS to apply an MFP adjustment. Regardless, they agree with the views of the Medicare Board of Trustees, per the 2018 Trustees Report, that unrealistic productivity gain targets could negatively impact beneficiaries' access to care and quality of service. The commenters encouraged CMS to work with the kidney care community to find a more appropriate adjustment and potentially encourage Congress to eliminate the MFP adjustment for ESRD facilities in the future.

Response: Section 1881(b)(14)(F)(i) of the Act requires the application of the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket update for 2012 and subsequent years. We will continue to monitor the impact of the payment updates, including the effects of the MFP adjustment, on ESRD provider margins as well as beneficiary access to care as reported by MedPAC. However, as mentioned, any changes to the productivity adjustment would require a change to current law.

In the March 2018 Report to Congress³, MedPAC found that outpatient dialysis payments

³ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch6_sec.pdf?sfvrsn=0

are adequate, noting positive indicators for beneficiaries' access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital.

While we understand that the kidney care community would like to find a more appropriate adjustment, such as an ESRD-specific MFP measure, we encourage commenters to discuss the feasibility of such measures with the Bureau of Labor Statistics, the agency that produces and publishes industry-level MFP. We would also refer commenters to the November 2006 article, "[Hospital Multifactor Productivity: A Presentation and Analysis of Two Methodologies](#)", published in the Health Care Financing Review⁴ that discusses challenges that exist in measuring health care specific multifactor productivity.

Finally, we understand that labor costs may be rising due to the tighter labor market and additional administrative costs resulting from QIP reporting requirements; however, we would remind commenters that these increased compensation pressures are taken into account within the annual market basket update. Increasing relative wage costs are reflected in a higher Wages and Salaries cost weight of 34.5 percent in the 2016-based ESRDB market basket compared to the 2012-based ESRDB market basket wage cost weight of 33.7 percent. Also, expected compensation pressures are taken into account via the annual forecasts of the price proxies for wages used in the annual payment update. The CY 2019 payment update of 2.1 percent reflects compensation prices increasing faster than the majority of the non-compensation price proxies, which is evident with a Compensation relative importance of about 45 percent in CY 2019 compared to the 2016 base weight of 43.6 percent. The relative importance reflects the different rates of price change for cost categories between the base year (2016) and CY 2019.

⁴ D Cylus, Jonathan & A Dickensheets, Bridget. (2006). Hospital Multifactor Productivity: A Presentation and Analysis of Two Methodologies. Health care financing review. 29. 49-64.

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

As a result of these provisions, the CY 2019 ESRDB market basket increase is 1.3 percent. This market basket increase is calculated by starting with the 2016-based ESRDB market basket percentage increase factor of 2.1 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 0.8 percentage point.

The CY 2019 ESRDB increase factor would be 0.1 percentage point higher if we used the 2012-based ESRDB market basket. That is, the CY 2019 ESRDB market basket increase factor is 1.4 percent using the 2012-based ESRDB market basket.

The comments and our response to the comments on the proposed CY 2019 market basket increase are set forth below.

Comment: Several commenters supported the proposed market basket update for CY 2019.

Response: We appreciate the commenters' support. The proposed 1.5 percent payment increase was based on IGI's 1st quarter 2018 forecast of the proposed 2016-based ESRDB market basket and the 10-year moving average of annual economy-wide private nonfarm business MFP. As noted in the proposed rule, if a more recent forecast of the market basket and MFP adjustment becomes available, we would use such data to determine the CY 2019 market basket update and MFP adjustment in the final rule. Based on IGI's more recent 3rd quarter 2018 forecast, we determined a payment increase of 1.3 percent for the final update percentage.

iii. Labor-Related Share for ESRD PPS

We define the labor-related share 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 proposed to use the 2016-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities. Therefore, effective for CY 2019, we proposed a labor-related share of 52.3 percent, slightly higher than the current 50.673 percent that was based on the 2012-based ESRDB market basket, as shown in Table 10. We proposed 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 ESRDB market basket.

TABLE 10: CY 2019 Labor-Related Share and CY 2018 Labor-Related Share

Cost Category	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 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).

The comments and our response to the comments on the proposed labor-related share for CY 2019 are set forth below.

Comment: Several commenters supported the proposal to increase the labor-related share for CY 2019 to 52.3 percent.

Response: We appreciate the commenters' support of the proposed labor-related share of 52.3 percent. This increase in the ESRD labor-related share reflects the relative increase in labor-related costs compared to non-labor-related costs that ESRD facilities have experienced since 2012.

After consideration of public comments, CMS is finalizing the labor-related share of 52.3 percent, as proposed.

b. The 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 updated 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 final CY 2019 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final 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, we refer readers to the 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 policy

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 0.55 and 0.50, 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), we decided to maintain a wage index floor of 0.40, rather than further reduce the floor by 0.05. We stated 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 ESRD PPS 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 0.40 in the CY 2017 ESRD PPS final rule (81 FR 77858).

In the CY 2018 ESRD PPS final rule (82 FR 50747), we finalized a policy to maintain

the wage index floor of 0.40 for CY 2018 and subsequent years, because we believed it was appropriate and continuing to provide 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 proposed to increase the wage index floor to 0.50. As we explained in the CY 2019 ESRD PPS proposed rule, this wage floor increase would be responsive to stakeholder comments, safeguard access to care in areas at the lowest end of the current wage index distribution, and be supported by data, as discussed below, which supports a higher wage index floor. We noted that stakeholders, particularly those located in Puerto Rico, have described 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 affect wages and salaries. For example, there is the potential of the outmigration of qualified staff that would cause a facility the need to change its hiring practices or increase the wages that it would otherwise pay had there not been a natural disaster.

We noted that in response to the CY 2018 ESRD PPS proposed rule, commenters described the economic and health care crisis in Puerto Rico and recommended that CMS use the United States (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. Commenters explained that 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 did not believe maintaining the current wage index for Puerto Rico for CY 2018 would be 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 in the CY 2018 ESRD PPS proposed rule, we maintained the wage index floor of 0.40 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. We also explained that 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 stated that we did not agree that the hospital-reported data is unreliable, and we believed using that data is more appropriate than applying the wage index value for the Virgin Islands where salaries are considerably higher.

We explained in the CY 2019 ESRD PPS proposed rule that 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. We stated that 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 0.40. The details of these analyses and our proposal for CY 2019 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 utilized data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015. We noted 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 Puerto Rico use of labor inputs.

The alternative wage indices derived from the analysis indicated that Puerto Rico's wage index likely lies between 0.51 and 0.55. Both of these values are above the current wage index floor and suggested that the current 0.40 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: $IQR = 0.9881 - 0.8303 = 0.1578$. Finally, we identified the inner fence values as shown below.

$$\text{Lower inner fence: } Q1 - 1.5 * IQR = 0.8303 - (1.5 \times 0.1578) = 0.5936$$

$$\text{Upper inner fence: } Q3 + 1.5 * IQR = .881 + (1.5 \times 0.1578) = 1.2248$$

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

Based on these analyses, we proposed a wage index floor of 0.50. We noted that we believe this increase from the current 0.40 wage index floor value minimizes the impact to the ESRD PPS base rate while providing increased payment to areas that need it. We considered the various wage index floor values based on our analyses. We noted that 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 0.40 and 0.55 and proposed 0.50 in an effort to strike a balance between providing additional payments to affected areas while minimizing the impact on the base rate. We stated that we believe the proposed 25 percent increase from the current 0.40 value would help to address stakeholder requests for a higher wage index floor, would minimize patient access issues, and would have a lower impact to the base rate than if we proposed a higher wage index floor value.

We noted that 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 0.40. The next lowest wage index is in the Wheeling, West Virginia CBSA with a value of 0.6598. Under our proposal, all CBSAs in Puerto Rico would receive the wage index floor of 0.50. Though the proposed wage index value currently affects CBSAs in Puerto Rico, we noted that, consistent with our established policy, any CBSA that falls below the floor would be eligible to receive the floor. We solicited comment on the proposal to increase the wage index floor from 0.40 to 0.50 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.iv of this final rule, we finalized the labor-related share of 52.3 percent, which is based on the final 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>. In the CY 2019 ESRD PPS proposed rule (83 FR 34330) we noted that 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 and stated that 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. However, we provided 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. We noted that 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 was 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 resulted in the proposed estimated wage index of 0.8335 for CBSA 46300.

We noted that in the final rule, we would incorporate this change into the final CY 2019 ESRD PPS wage index, rate setting and Addenda. Thus, for CY 2019, we are using 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.

The comments and our responses to the comments on our proposed revisions to the wage index floor are set forth below.

Comment: MedPAC commented that its standing position, as stated in its June 2007 report to the Congress, is that creating rural floors and implementing other changes (for example, exceptions and reclassifications) to a wage index system distorts area wage indexes. In addition, the Commission stated that the current ESRD PPS wage index is flawed in that it is based only on data from hospitals, rather than data for all of the health care providers in a given market. In place of using the hospital wage index for ESRD facilities, MedPAC recommended that CMS establish an ESRD PPS wage index for all ESRD facilities (not just those located in Puerto Rico) that: (1) uses wage data representing all employers and industry-specific occupational weights; (2) is adjusted for geographic differences in the ratio of benefits to wages; (3) is adjusted at the county level and smooths large differences between counties; and (4) is implemented so that large changes in wage index values are phased in over a transition period.

MedPAC commented that this alternative approach to the wage index is based on wage data from BLS and the Census Bureau, and benefits data from provider cost reports submitted to CMS. The Commission noted that CMS's analysis of alternative wage indices (ranging between 0.510 and 0.550) for Puerto Rico also combined labor data from provider (ESRD facilities) cost reports with BLS wage information and recommended CMS provide additional documentation of its analysis to determine the two alternative wage indices for Puerto Rico.

Response: As described in the CY 2019 ESRD PPS proposed rule (83 FR 34328 through 34330), the analysis we conducted to test the reasonableness of the current wage index floor used wages from the BLS and full-time equivalents (FTEs) by occupation reported on the cost reports for independent facilities. Specifically, we calculated labor weights by occupation for Puerto Rico and the greater U.S. as the treatment-weighted average of the FTEs reported on independent facility cost reports. We did not include hospital-based cost report data because the occupations

for which the FTEs were reported were not identical between independent and hospital-based cost reports (for example, hospital cost reports do not have FTEs for administrative and management staff associated with renal units). Although we used the wages from the BLS data, we did not use benefits data and therefore we did not adjust for geographic differences in the ratio of benefits to wages.

The values of 0.510 and 0.550 are the calculated 2015 wage index values based on the use of FTEs specific to Puerto Rico and the greater U.S., respectively. The 2015 wage index based on Puerto Rico FTEs is a standard Laspeyres price (wage) index that used quantity weights from the reported composition of FTEs in Puerto Rico, such that the wage index can be represented as the FTE-weighted sum of Puerto Rico wages by occupation divided by the FTE-weighted sum of U.S. wages by occupation. Note that the numerator and denominator in this formula use the same FTEs. Similarly, we constructed the 2015 wage index based on U.S. FTEs as a standard Laspeyres price index using quantity weights from the reported composition of FTEs in the U.S. The wage index value in each of these calculated indices exceeds the current wage floor, suggesting that the current wage index may not adequately capture the full cost of labor at dialysis facilities operating in Puerto Rico. Also, we did not calculate the wage index at the county level because the analysis was aimed at calculating a single wage index for all of Puerto Rico. We appreciate MedPAC's feedback on the current wage index and suggestions for establishing a new wage index for the ESRD PPS and will consider the Commission's recommendations for future rulemaking.

Comment: Several commenters, including a national dialysis provider organization, two LDOs, and an insurance company expressed support for the proposal to increase the wage index from 0.40 in 2018 to 0.50 in 2019, because they believe it will assist dialysis clinics in providing

access to high-quality care particularly in rural areas where access challenges may be present.

Another insurance company urged CMS to take another look at the amount of the wage index increase. This commenter pointed out that in the proposed rule, CMS noted that its analysis indicates that the wage index in Puerto Rico likely lies between 0.51 and 0.55. The commenter urged the adoption of the 0.55 level as most accurately reflecting the post-hurricane wage environment, which includes provider migration and higher costs for capital and utilities.

A coalition of Puerto Rico stakeholders and a dialysis organization expressed support for CMS's position that the current wage index floor is too low and steps should be taken to increase it. While they appreciate any increase in ESRD fee for service (FFS) rates that move payment closer to a level where providers can cover costs, they stated CMS has an opportunity to further narrow the gap between FFS rates and costs in Puerto Rico so that ESRD providers are not wholly dependent on rates from Medicare Advantage plans to sustain operations. The dialysis organization stated that while an incremental increase would move the gauge toward better alignment with costs, the 0.50 falls far short, and would perpetuate a cycle of rate challenges for the healthcare stakeholders and high dialysis patient mortality and hospitalization rates.

The stakeholders recommended CMS evaluate increasing the floor to 0.70 to mitigate the distance of payments for dialysis services in critical areas relative to the range of wage index levels across the nation. They pointed out this amount is still lower than most jurisdictions, including the U.S. Virgin Islands, but could support a tangible and meaningful change in FFS payments considering the need for these services, as Puerto Rico goes through a crucial disaster recovery period. The stakeholders asserted that this wage index floor is necessary to reduce the flight of health care providers out of Puerto Rico, and this level of wage index floor would be related to actual wage indices in the states. The commenters stated that CMS should use its

administrative authority to adjust payment formulas in Puerto Rico to address the endemic problems in the health care system: provider migration due to low wages and reimbursement; poor infrastructure; higher costs for capital and utilities. The commenter estimated increasing the wage index floor to 0.70 could raise the Puerto Rico ESRD PPS rate to approximately \$200 to \$212 per episode, which would represent an approximate 18 percent increase over the 2018 rate.

At a minimum, they recommended CMS set the wage index floor at 0.5936, which was identified as the lower boundary of CMS's statistical outlier analysis. They also recommended CMS conduct a new survey on ESRD wages in Puerto Rico that distinguishes inpatient facility wages from outpatient facility wages, and recognizes the value of proposed increases on all the high cost health care factors faced by Puerto Rico in the wake of Hurricanes Irma and Maria. They pointed out the professional scope of practice for technicians is different between inpatient and outpatient facilities in Puerto Rico. They noted that while such technicians are permitted to assist in ESRD care under the supervision of an RN in inpatient facilities, this is not the case in outpatient facilities where RNs must provide all the care per local scope of practice laws. Therefore, to get a fully accurate projection of wage costs for ESRD providers in Puerto Rico, they recommended CMS evaluate inpatient and outpatient facility data separately.

A dialysis provider also stated the recruitment of bilingual staff and the shortage of bilingual RN's is a huge challenge. They pointed out the databases and websites used by all facilities are all English based and facilities must hire additional staff to work around the language barriers, and the current methodology and payment policies do not capture this anomaly. Although they expressed support for the wage index floor increase from 0.40 to 0.50, they pointed out CMS's analysis shows that Puerto Rico's wage index "likely lies between 0.51

and 0.55", while additional analyses note that any wage index values less than 0.5936 are considered outlier values, with 0.5936 therefore as the lower wage index boundary. They expressed concern that CMS proposed a new floor of only 0.50 despite CMS's own analyses and recognition that the present methodology applied to Puerto Rico has created the only outlier in the U.S.

Response: As we stated in the CY 2019 ESRD PPS proposed rule, we continue to believe that a wage index floor of 0.50 strikes an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. The analyses were conducted to gauge the appropriateness of the current wage index floor and determine whether it is too low; we did not propose to use these analyses to determine the exact value for a new wage index floor. Instead, we considered these analyses along with the hospital wage data to determine an appropriate policy for a wage index floor. The purpose of the wage index adjustment is to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located. While a wage index floor of 0.50 would continue to be the lowest wage index nationwide, we note that the areas subject to the floor continue to have the lowest wages compared to mainland facilities. We note that an increase to the wage index floor to 0.50 is a 25 percent increase over the current floor and will provide a higher wage index for all facilities in Puerto Rico where wage indexes, based on hospital reported data, range from .33 to .44. For these reasons, we believe a wage index floor of 0.50 is appropriate and will support labor costs in low wage areas.

With regard to concerns raised about the need to hire bilingual RNs, the need for bilingual staff occurs in both inpatient and outpatient settings and hospital cost reports should reflect those additional costs. We note that in every analysis we conducted, the average salary of

RNs in Puerto Rico was approximately half that of mainland facilities and none of the analyses produced a 0.70 wage index value. We do not believe it is appropriate to raise the wage index floor to 0.70 in order to mitigate non-labor losses from the disaster. The wage index adjustment is intended to recognize geographic differences in wage levels in areas in which ESRD facilities are located. As such it would not be appropriate to utilize the wage index floor policy to address infrastructure, capital, and other non-labor related costs.

With regard to the use of RNs in Puerto Rico facilities, we have received conflicting information from Puerto Rico about the how local scope of practice for RNs and other staff impact ESRD facility costs. We are continuing to explore alternative methodologies for accounting for the labor-related costs of all Medicare providers and we may revisit the use of a wage index floor under the ESRD PPS in that context.

Final Rule Action: After considering the public comments we received regarding the wage index floor, we are finalizing an increase to the wage index floor from 0.40 to 0.50 for CY 2019 and subsequent years as proposed. 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. For CY 2019, the labor-related share to which a facility's wage index is applied is 52.3 percent, based on the finalized 2016-based ESRDB market basket which is discussed in section II.B.2 of this final rule.

c. Final 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 proposed 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 proposed 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 stated in the CY 2019 ESRD PPS proposed rule that 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.

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

For this final 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 2018 with the updated final estimates for this rule. The estimates for the final 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 final 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	\$34.18	\$40.18
Adjustments				
Standardization for outlier services	1.0177	0.9774	1.0503	0.9779
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$37.31	\$42.41	\$35.18	\$38.51
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$47.79	\$77.54	\$57.14	\$65.11
Patient-month-facilities qualifying for outlier payment	9.0%	7.4%	7.2%	8.2%

As demonstrated in Table 11, the estimated FDL amount per treatment that determines the CY 2019 outlier threshold amount for adults (Column II; \$40.18) is lower than that used for the CY 2018 outlier policy (Column I; \$44.27). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from \$42.41 to \$38.51. For pediatric patients, there is an increase in the FDL amount from \$47.79 to \$57.14. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from \$37.31 to \$35.18.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2019 will be 8.2 percent for adult patients and 7.2 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. For this final rule and 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 final 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.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: Although we did not propose changes to the outlier target percentage or methodology for computing the MAP or FDL amounts, we received many comments regarding

the difference between estimated outlier payments and the 1.0 percent outlier target.

An LDO and a patient advocacy organization pointed out that since its inception, the outlier policy has not consistently achieved parity in distributing dollars withheld to fund the pool. The commenters stated that although the undistributed outlier pool dollars may not represent a significant amount per treatment, their analyses estimate that since 2011, \$5.48 per treatment has been removed from the ESRD PPS by outlier pool underpayments. They noted that the outlier pool's imperfect performance further supports their view that it is inappropriate to extend the outlier policy to new drugs and biologicals upon the expiration of the TDAPA. The patient advocacy organization stated that although the use of updated claims data has led to small improvements, the persistent gap indicates the need for additional efforts to achieve parity and end what the organization views as inappropriate reductions to ESRD PPS payments. The organization stated paying out any remaining outlier pool dollars to providers in a subsequent year should be a central part of those efforts.

A dialysis provider organization urged CMS to reconsider the 1 percent outlier policy and pointed out while an outlier adjustment is required under the statute, it does not specify a particular value. The organization stated a 0.5 percent outlier threshold would reduce the offset to the base payment and still provide for payment in the case of extraordinary costs. A national dialysis organization, as part of its comment on the outlier expansion comment solicitation, expressed concern that the outlier policy continues to underestimate the outlier payment actually paid out each year since 2011, and believes money has been inappropriately removed from the ESRD PPS overall funding that is not returned to the system. For example, the organization noted the change from 2017 to 2018 is only 0.78 to 0.80. Over time, the organization estimates that the amount has resulted in a loss of \$67 million since 2015 and \$231 million since 2011.

Response: We appreciate the suggestions provided. We continue to believe that 1.0 percent is an appropriate target for outlier payments and that the recalibrated thresholds will lead to increased payments that are closer to the 1.0 percent target. A 1.0 percent outlier target percentage is a modest amount in comparison to other Medicare prospective payment systems and helps ensure high cost patients receive the individualized services they need. We disagree that a .50 percent threshold is more appropriate since the outlier payments represent .80 percent of total payments, close to the 1.0 percent target. We will, however, take the commenters' views into consideration as we explore ways to enhance and update the outlier policy.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2019 displayed in Column II of Table 11 of this final rule and based on CY 2017 data.

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 supporting innovation, ensuring appropriate payment for all drugs and biologicals, and as a complement to the TDAPA proposals, in the CY 2019 ESRD PPS proposed rule, we solicited comment on whether we should expand the outlier policy to include composite rate drugs and supplies (83 FR 34332). We noted that under the proposed expansion to the drug designation process, such expansion of the outlier policy could support 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 support use of new innovative devices or items that would otherwise be considered in the ESRD PPS bundled payment. We stated that if commenters believe such an approach is appropriate, we requested 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 specifically requested feedback about how such items might work under the existing ESRD PPS outlier framework or whether specific changes to the policy to accommodate such items are needed. We stated that we will consider all comments and address them by making proposals, if appropriate.

A summary of the comments we received and our response to the comments are set forth below.

Comments: A dialysis provider association supported the proposed expansion of the outlier policy to include drugs, biologicals, and supplies that currently fall into the ESRD PPS composite rate. The association strongly agreed with CMS that an expansion of the outlier policy would promote and incentivize the development of innovative new therapies and devices to treat the highly vulnerable ESRD adult and pediatric patient populations, and therefore urged CMS to propose such an expansion in future rulemaking. The association further suggested that CMS include a line in the claim for identification of supplies for outlier payment, explaining that having this information on the claim would both ease administrative burden and improve payment accuracy.

A dialysis provider organization commented that within the context of an expanded TDAPA policy, including formerly composite rate drugs within the outlier calculation in the future would be a positive step, even if a new drug added to the ESRD PPS bundled payment includes additional payment. The organization stated if a new drug is folded into an existing ESRD PPS functional category without additional payment, providing outlier eligibility to these drugs could be even more important. The organization also indicated that collecting the data necessary to implement such a policy may have merit and encouraged CMS to continue to seek

stakeholder input in future rulemaking in the context of whatever final policy it establishes for an expanded TDAPA in this year's CY 2019 ESRD PPS final rule.

A health plan encouraged CMS to propose changes to the outlier policy that would take into account composite rate drugs and supplies because the health plan believes all costs of treating a patient should be included when determining outlier payments. The health plan pointed out that many patients who receive composite rate drugs and supplies have complex needs due to non-compliance or comorbid conditions and excluding composite rate drugs and supplies could discourage ESRD facilities from accepting higher acuity patients.

An LDO commented that it does not support the proposal to expand the outlier policy to include composite rate drugs and supplies and would prefer the outlier payment adjustment be removed from the ESRD PPS. The LDO expressed concern that money is being taken out of the system that is never returned to support patient care and expanding this policy will only make matters worse. The LDO understands the agency would require statutory authority to eliminate the outlier provision, however, it stated CMS does have discretion to reduce the size of the outlier pool and recommended CMS decrease the outlier percentage from 1 percent to 0.5 percent.

A national LDO and a national dialysis organization stated the outlier pool cannot provide adequate reimbursement for costly new drugs and biologicals in the ESRD PPS. In the national dialysis organization's view, outlier payments are not designed to pay for drugs. They are meant for patients with unusually high costs. The LDO noted that while the outlier pool had an early connection to beneficiaries who were high utilizers of certain high-cost drugs and biologicals in the ESRD PPS bundled payment, specifically ESAs, the outlier pool was never designed to provide comprehensive reimbursement for such products. Rather, the LDO stated,

CMS incorporated funding for ESAs into the ESRD PPS base rate and the small number of individuals whose ESA utilization was a true outlier would then qualify for an outlier payment in addition to what was already built into the base rate for the average patient. Both commenters expressed that expanding the outlier pool would still not address the need for money to be added to the base rate.

The national dialysis organization does not support extending the outlier payment to new drugs or biologicals that CMS would classify as being within the existing ESRD PPS functional categories. The organization believes it would be inappropriate to do so because outlier payments are not designed to pay for drugs and biologicals used regularly.

MedPAC commented that an outlier policy should act as a stop-loss insurance for medically necessary care, and outlier payments are needed when the PPS's payment adjustments do not capture all of the factors affecting providers' costs of delivering care. For example, MedPAC stated, when higher costs arise due to the occurrence of random events, such as patients who suffer serious complications, then outlier payments would be appropriately triggered. Consequently, MedPAC noted in order to develop an effective outlier policy, CMS must first develop accurate patient- and facility-level payment adjustments.

Further, MedPAC indicated CMS should develop an outlier policy that accounts for variation in the cost of providing the full ESRD PPS payment bundle; the outlier policy should not apply solely to exceedingly high costs of ESRD drugs and supplies. MedPAC stated that this approach would be more patient-centric and would align the ESRD PPS outlier policy with the policies of other Medicare PPSs.

However, MedPAC cautioned if CMS elects to expand the outlier pool only for composite rate drugs and supplies, then the agency should explicitly define which supplies would

be eligible for an outlier payment. In addition, MedPAC recommended that the agency should develop clinical criteria for the use of all drugs and supplies eligible for outlier payments to ensure their appropriate (medically necessary) use.

MedPAC noted that expanding the outlier policy may require the agency to impose additional reporting requirements on facilities in order to determine patient-level costs. Should the agency elect to expand the outlier policy, MedPAC recommended minimizing the administrative burden on providers and including a mechanism for validating the additional collected data.

Response: We appreciate the thoughtful responses from the commenters. We recognize that the commenters' concerns regarding the expansion of outlier eligibility to include composite rate drugs and supplies are inextricably linked to their views on the effectiveness of our broader outlier policy or other payment adjustments. We will take these views into account as we consider the outlier policy and payment adjustments for future rulemaking.

d. Final 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, training adjustment add-on, and transitional drug add-on payment adjustment.

ii. Annual Payment Rate Update for CY 2019

The ESRD PPS base rate for CY 2019 is \$235.27. 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 final ESRDB market basket is 2.1 percent. In CY 2019, this amount must be reduced by the multifactor 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 final MFP adjustment for CY 2019 is 0.8 percent, thus yielding a final update to the base rate of 1.3 percent for CY 2019 ($2.1 - 0.8 = 1.3$). Therefore, the ESRD PPS base rate for CY 2019 before application of the wage index budget-neutrality adjustment factor would be \$235.39 ($\$232.37 \times 1.013 = \235.39).

- 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 did not propose 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). The final CY 2019 wage index budget-neutrality adjustment factor is 0.999506, based on the updated wage index data. This application would yield a final CY 2019 ESRD PPS base rate of \$235.27 ($\$235.39 \times 0.999506 = \235.27).

The comments and our responses to the comments on our proposals to update the ESRD PPS base rate for CY 2019 are set forth below.

Comment: A dialysis provider organization expressed appreciation for the proposed increase to the ESRD PPS base rate for CY 2019 but stated the increase is insufficient to cover the annual growth in costs for dialysis facilities necessary to offer life-sustaining, high-quality care to pediatric and adult ESRD patients. The organization noted that this is a concern for small and independent providers in rural and underserved areas, and can significantly impact whether a facility remains open. Therefore, the organization believes an appropriate increase in overall reimbursement is required.

A clinician association stated that while it appreciates the proposed increase to the ESRD PPS base rate, the association is concerned about other policies in the ESRD PPS and ESRD QIP that may result in reductions to the already limited resources used by nephrology nurses to provide high quality care to Medicare ESRD beneficiaries.

The association stated that since the implementation of the ESRD PPS, nephrology nurses have been required to balance the constant increases in demands for data collection and the time required to provide quality patient care to a population of individuals with complex care needs. The commenter explained nephrology nurses understand the increased

administrative burden placed on dialysis facilities in meeting regulatory documentation requirements and are often the collectors and providers of this data at the unit level.

We received many comments, including from MedPAC, national kidney dialysis organizations, professional associations, patient advocacy organizations, LDOs, and a health plan, related to the current ESRD PPS patient and facility-level adjustments and the negative impact these adjustment factors have on the ESRD PPS base rate due to the standardization adjustment.

Response: We appreciate the support for the increase in the ESRD PPS base rate and the comments regarding the issues impacting ESRD facilities. We understand facilities in rural and underserved areas face unique challenges. We also recognize the administrative work done by the nephrology nurses. We note that in a PPS, the payment is for the average patient and the facility and patient adjusters attempt to mitigate any loss by those at the lower end of the payment spectrum.

As we stated in section II.B.3.d.i of this final rule, we established an ESRD PPS base rate that reflected the lowest per patient utilization data as required by statute. This amount is adjusted for patient specific case-mix adjustments, applicable facility adjustments, and geographic difference in area wage levels which are reflective of facility costs since cost data is used to derive the adjustment factors. The CY 2016 ESRD PPS final rule discusses the methodology for calculating the patient and facility-level adjustments (80 FR 68972 through 69004). In addition, the base rate is adjusted for any applicable outlier payment, training add-on payment, and the TDAPA to arrive at the per treatment payment amount. The ESRD PPS base rate is annually updated by the ESRDB market basket and adjusted for productivity and wage index budget neutrality. For these reasons, we believe that the CY

2019 ESRD PPS base rate is appropriate despite the challenges some facilities experience. We also continue to believe that the rural adjustment and LVPA provide payment for the challenges faced by those facilities that are eligible for the adjustment. We note that the ESRDB market basket for CYs 2015 through 2018 was reduced in accordance with section 217(b)(2) of PAMA and for CY 2019, ESRD facilities are getting the full ESRDB market basket update, which increases payment.

The comments on the current ESRD PPS patient and facility-level adjustments based on the regression analysis are out of scope for this final rule since we proposed changes to the administration of certain adjustments (that is, LVPA and comorbidities), but did not propose any changes related to the calculation of these adjustments. However, we will continue to consider these comments for future refinements to ESRD PPS policies. Additionally, we are undertaking a new research effort and plan to engage with stakeholders further on this issue

Final Rule Action: We are finalizing a CY 2019 ESRD PPS base rate of \$235.27.

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.⁵ Therefore, as discussed in section IV.C.1.a. of section IV “End-Stage Renal Disease Quality Incentive Program (ESRD QIP)” of the CY 2019 ESRD PPS proposed rule (83 FR 34344), we proposed 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 also solicited 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

⁵ 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.

services adequately, or should additional requirements be considered?

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 patients⁶. 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

⁶ 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 welcomed your suggestions on ways to ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities.

In the proposed rule we reviewed the importance of treatment modality options and education for individuals with failed kidneys, including transplantation and home dialysis, and the related CfC standards that dialysis facilities must meet. We requested suggestions on other

ways to increase kidney transplant referrals and improve the tracking process for patients on the waitlist. We also asked for input on ways to better ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities. We received extensive comments on these issues from approximately 20 stakeholders. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their input.

D. Miscellaneous Comments

We received many comments from beneficiaries, physicians, professional organizations, renal organizations, and manufacturers related to issues not specifically addressed in the CY 2019 ESRD PPS proposed rule. These comments are discussed below.

Comment: A device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new FDA-approved medical devices. They commented on the lack of FDA approved or authorized new devices for use in a dialysis facility, highlighting the need to promote dialysis device innovation for use by dialysis clinics. The commenters indicated they believe the same rationale CMS used to propose broadening the TDAPA eligibility also would apply to new medical devices. Specifically, the commenters noted the statute provides CMS with "discretionary authority" to adopt payment adjustments determined appropriate by the Secretary, and precedent supports CMS' authority to use non-budget neutral additions to the base rate for adjustments under specific circumstances. The commenters asserted CMS could finalize this adjustment in the CY 2019 ESRD PPS final rule. A professional association urged CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the ESRD PPS bundled payment. They believe new money must be made available to appropriately reflect the cost of new devices

added to the ESRD PPS bundled payment.

A national dialysis organization and an LDO asked CMS to clarify how it incentivizes the development of new dialysis devices. The organization asked CMS to describe how such a device would be included in the ESRD PPS bundle, and suggested the initial application of a pass-through payment which would be evaluated later, based on the data. This evaluation would determine if the device should be included in the ESRD PPS base rate and whether or not additional funds should be added to the bundle. The organization offered to engage with CMS to develop a more detailed policy, but in the short-term, asked CMS to indicate in the final rule that it will provide such a pathway and work with stakeholders in future rulemakings to further define it.

An LDO requested CMS plan appropriately for innovative devices or other new innovative products. However, as the unfolding of the drug designation process has demonstrated the complexity of the process, the commenter noted the process should be both thoughtful and collaborative. The commenter asked CMS to work with the kidney community to consider if and how new devices or other new innovative products delivering high clinical value, can be delivered to beneficiaries, whether through the ESRD PPS or through other payment systems.

A home dialysis patient group also expressed concern regarding the absence of a pathway or guidance for adding new devices to the ESRD PPS bundled payment or for reimbursement, stating that it left investors and industry wary of investing in the development of new devices for patients.

Response: We appreciate the commenters' thoughts regarding payment for new and innovative devices, either via a TDAPA for medical devices or a pass-through payment for

medical devices. We also appreciate the commenter's comments regarding the complexity of such an adjustment as well as the concerns related to a lack of pathway for new devices. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: MedPAC strongly encouraged CMS to accelerate completion of the ESRD facility cost report audits and release its final results. MedPAC has repeatedly discussed the importance of auditing the cost reports dialysis facilities submit to CMS to ensure the data are accurate. MedPAC made the following points: First, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors and ESRD market basket index, which are derived from this data source. Second, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Third, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Fourth, historically, facilities' cost reports have included costs Medicare does not allow.

Response: We appreciate MedPAC's thoughts and suggestions on our cost reports and audits. The audit process is complete and the audit staff are reviewing the findings. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: An LDO stated excluding the 50-cent network fee from dialysis facilities' cost reports remains problematic, explaining that failure to account for the fee understated

facilities' costs by more than \$20 million in 2017 and inhibits informed policymaking. The commenter noted that in response to a prior recommendation on this issue, CMS suggested it does not have the statutory authority to include the network fee on cost reports. However, this commenter stated the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), which established the network fee, does not address its inclusion or exclusion. The House Report accompanying OBRA 86 elaborates on Congressional intent with respect to the network fee, but it too does not address the fee's inclusion or exclusion. The organization urged CMS to reexamine its interpretation of the statute, which they believe affords CMS the necessary authority to add the network fee as a revenue reduction on Worksheet D effective with CY 2019 dialysis facility cost reports. A national LDO organization made a similar comment.

Response: We appreciate the feedback regarding the 50-cent network fee and its inclusion in the cost reports. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: An LDO stated several years have elapsed since CMS eliminated the medical director fee limitation, but the ESRD Medicare Claims Processing Manual instructions, despite being updated in November 2016, do not reflect this policy change. Some Medicare contractors incorrectly continue to require dialysis facilities to submit detailed physician logs and apply the fee. The organization urged CMS to resolve this small, administrative matter to ensure the even application of its long-standing decision to eliminate the medical director fee limitation.

Response: The ESRD Medicare Claims Processing Manual (Pub 100-02 Section 40.6) was updated via Change Request 10541 (transmittal 4010) effective June 26, 2018.

Comment: An LDO stated the claim submission requirement to report the amount of an

oral equivalent used by an ESRD patient, not the amount dispensed, presents significant challenges for dialysis facilities. The organization noted that changes in a patient's condition may require a different course of treatment that calls for a lower or higher dose than initially recommended. Other common circumstances, such as a patient's relocation, necessitating the delivery of services at a different, geographically closer facility, further complicate compliance with the reporting requirement. The organization recommended CMS modify the current requirement and permit dialysis facilities to report the dispensed amount of an oral drug. The organization suggested the following revised requirement: CMS should permit dialysis facilities to claim products dispensed in good faith, even if discarded, because of death, change in prescription, transfer to another facility, hospitalization, or transplant. CMS also should cover any replacement medication should the beneficiary lose it.

Response: We appreciate the commenter's feedback on the reporting of oral equivalent drugs. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: We received comments on home dialysis from several different commenters, including patient advocacy groups, national kidney organizations, a national LDO organization, dialysis provider associations, dialysis equipment manufacturers, and a large number of beneficiaries. These commenters called for modifications or rescission of the Medicare Administrative Contractor proposed Local Coverage Determinations, in order to remove uncertainty in reimbursement for more frequent dialysis for home dialysis patients. They urged CMS to ensure all MACs abide by the requirements included in the Medicare Program Integrity Manual in implementing policies regarding payment for more frequent dialysis. They expressed strong support for efforts to increase access to home dialysis for patients for whom it is

medically appropriate. Additionally, they encouraged CMS to eliminate ambiguity in past rulemaking regarding CMS' payment policy for medically justified more frequent hemodialysis sessions, to provide clear and correct information for the MAC's understanding and for providers who may be inadvertently discouraged from informing patients of all suitable treatment options.

Response: We appreciate the commenters' thoughts on home dialysis. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: We received many other comments that we consider outside the scope of the CY 2019 ESRD PPS proposed rule, including the following suggestions: incorporation of the CFC requirement to document why a patient is not a candidate for home dialysis on the UB-04 claims; modification of the kidney dialysis education program so it may be practically implemented and more broadly utilized; and reinforcement of providers' responsibility to inform Skilled Nursing Facility (SNF) dialysis patients of their option to perform home dialysis in a SNF, and a reminder to providers to appropriately code their home dialysis patients residing in SNFs to allow for better population surveillance.

Response: We appreciate receiving these comments regarding issues affecting ESRD facilities and beneficiaries. However, we did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

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), Pub. 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.

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. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on CY 2019 Payment for Renal Dialysis Services Furnished to Individuals with AKI

The proposed rule, titled “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” (83 FR 34304 through 34415), hereinafter referred to as the “CY 2019 ESRD PPS proposed rule”, was published in the **Federal Register** on July 19, 2018, with a comment period that ended on September 10, 2018. In that proposed rule, we proposed to update the AKI dialysis payment rate. We received approximately 7 public comments on our proposal, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2019 payment for renal dialysis services furnished to individuals with AKI.

C. 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 the CY 2019 ESRD PPS proposed rule (83 FR 34332 through 34333), the CY 2019 proposed ESRD PPS base rate was \$235.82, which reflected the proposed ESRD bundled market basket and multifactor productivity adjustment. Therefore, we proposed 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 the CY 2019 ESRD PPS proposed rule (83 FR 34332). 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. We proposed a CY 2019 AKI dialysis payment rate of \$235.82, adjusted by the ESRD facility's wage index.

The comments and our responses to the comments on the AKI payment proposal are set forth below.

Comment: A national dialysis organization expressed appreciation that CMS announced

the AKI payment rate as part of the CY 2019 ESRD PPS proposed rule and provided the kidney care community with the opportunity to provide comments on the recommendations.

A dialysis provider association urged CMS to increase payments for AKI treatments to be consistent with its analysis of preliminary 2017 cost report data showing that average costs for an AKI treatment are nearly \$50 (about 19 percent) higher than average costs for in-center hemodialysis patients. In the analysis, 1,524 of a total of 5,255 freestanding facilities reported AKI treatments. The association explained that the nearly \$50 higher per treatment costs for AKI versus in-center maintenance dialysis were driven by the higher direct patient care staffing needs for AKI patients (4.0 staff hours per treatment) compared to maintenance dialysis (2.5 staff hours per treatment). Additionally, laboratory costs (\$4.93 vs. \$3.91) and administrative and general services costs (\$80.06 vs. \$65.48) were higher for AKI treatments than for in-center maintenance hemodialysis treatments.

Given that the facility costs vastly exceed payment rates for AKI treatments on average, the association urged CMS to increase the AKI payment rate and make appropriate payment adjustments for case-mix, comorbidities, and others (described below) to more accurately account for the costs that facilities bear when treating AKI patients. The association stated that it believes with more accurate and adequate reimbursement it is likely more dialysis facilities will be able to extend dialysis treatment access to AKI patients in a generally lower cost setting than the outpatient hospital setting, where many AKI patients currently receive treatment.

The association also requested that CMS establish payment adjusters beyond the wage index in order to ensure that facilities have sufficient resources to provide high-quality care to AKI patients, including the following:

- **Low-volume adjustment:** The association noted that facilities with low treatment volumes face similar cost challenges in providing dialysis to AKI and ESRD patients. The relatively high fixed costs in operating a dialysis clinic are more difficult to offset in facilities with low treatment volume. Therefore, the association urged CMS to apply a low-volume adjustment to AKI treatments for patients in low-volume facilities.
- **Pediatric adjustment:** The association stated that similar to pediatric patients with ESRD, pediatric patients with AKI experience costly treatment challenges that are unique and distinct from the adult AKI patient population. As such, the association urged CMS to adopt a pediatric adjustment to the AKI payment rate for facilities treating pediatric AKI patients.
- **A rural adjustment factor:** The association noted that this should be added to the AKI payment rate to account for the additional treatment costs incurred by rural facilities. The association also asked CMS to review the CBSA methodology used for purposes of the rural adjustment, which prevents units that reside within a county that is rural from receiving the adjustment if the CBSA in which they reside is deemed urban.

Response: We appreciate the support from commenters with regard to our CY 2019 per treatment base rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. We also appreciate the feedback on the costs associated with an AKI treatment as compared to an ESRD treatment. We note that the Independent Renal Dialysis Facility Cost Report (Form CMS-265-11) was revised in February 2018 for AKI renal dialysis services furnished on and after January 1, 2017 (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4PR242.pdf>). We will use the data reported

on this form to review the efficacy of the AKI payment rate and determine the appropriate steps toward further developing the AKI payment rate.

We also appreciate the commenters' feedback on the application of the LVPA, pediatric, and rural adjustments to AKI dialysis treatments. In the CY 2017 ESRD PPS final rule (81 FR 77868), we discussed not applying the case-mix adjusters to the payment for AKI treatments because those adjusters were developed based on ESRD treatments, and we continue to believe this is the most appropriate policy at this time. As we continue to monitor data, we will review the efficacy of the AKI payment rate to determine if modification is required.

We also received comments related to monitoring programs, data collection, budget neutrality, inclusion of AKI in the ESRD QIP, questions related to a patient's transition from AKI to ESRD and eligibility for transplant, home dialysis for AKI patients, and other operational concerns. We did not include any proposals on these topics in the proposed rule, and therefore we believe these comments are out of scope for this rulemaking. However, we will consider these comments for future refinements to AKI payment policies.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, based on the finalized ESRD PPS base rate. Specifically, the final CY 2019 ESRD PPS base rate is \$235.27. Accordingly, we are finalizing a CY 2019 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as \$235.27.

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

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (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).

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Newly Finalized Policies for the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

The proposed rule, titled “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” (83 FR 34304 through 34415), hereinafter referred to as the “CY 2019 ESRD PPS proposed rule”, was published in the **Federal Register** on July 19, 2018, with a comment period that ended on September 10, 2018. In that proposed rule, we proposed updates to the ESRD QIP, including for PY 2021 through PY 2024. We received approximately 36 public comments on our proposal, including comments from large dialysis organizations, renal dialysis facilities, national renal groups, nephrologists, patient organizations, patients and care partners, health care systems; nurses, and other stakeholders.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ESRD QIP.

We received numerous general comments on the ESRD QIP.

Comment: Commenters provided feedback on adding new measures to the QIP.

Commenters’ suggestions for new measures included a standardized mortality measure, outcome

measures that can replace existing process measures, a measure of shared decision-making, two process measure for evaluating the share of patients receiving dialysis modality education (one measure focusing on education within 90 days of initiating dialysis and a second measure focusing on annual education). Another commenter recommended that CMS allow providers to test upcoming changes or software updates to CROWNWeb and the ESRD QIP system.

Response: We appreciate these comments and thank the commenters for their feedback.

We will consider these comments for future rulemaking.

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.⁷ This initiative is one component of our agency-wide Patients Over Paperwork Initiative,⁸ which is aimed at evaluating and streamlining 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

⁷ Meaningful Measures webpage: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

⁸ 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>.

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 discussed in the CY 2019 ESRD PPS proposed rule that we had 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

Quality Priority	Meaningful Measure Area
	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
Make Care Affordable	Community Engagement
	Appropriate Use of Healthcare
	Patient-focused Episode of Care
	Risk Adjusted Total Cost of Care

By including Meaningful Measures in our programs, we stated our belief 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 also stated that 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.

The comments and responses to the Meaningful Measure Initiative are set forth below.

Comment: Many commenters were pleased with our launch of the Meaningful Measures Initiative. One commenter expressed support for our aim to focus the Program on the highest priority areas for quality measurement and quality improvement. The commenter recommended that we differentiate between the ESRD QIP, a pay-for-performance or value-based purchasing (VBP) program, and Dialysis Facility Compare (DFC), a public reporting site. The commenter suggested that the relationship between these two programs is confusing and called on CMS to

separate the programs clearly by using different measures in each program, using star ratings based on the ESRD QIP payment penalties, and improving the DFC website's functionality. Another commenter urged CMS to be cognizant of the unfunded regulatory burden on dialysis facilities to track and monitor QIP measures and recommended aligning measures in QIP with those in Dialysis Facility Reports (DFR), DFC, and Core Survey, suggesting that facility burden is significant, and using a single website such as the ESRD Quality Reporting System (EQRS) to track and report data for all programs. Another commenter appreciated our interest in focusing the Program on measures that improve quality care, drive improved patient health outcomes, and reduce administrative burdens on providers, but was concerned with the overlap between the ESRD QIP, the Five Star Program, and DFC. The commenter recommended that we streamline the ESRD QIP and reduce the Program's administrative burden and promote transparency.

Response: We appreciate and thank the commenters for their feedback and support of the Meaningful Measures Initiative, and we will consider this feedback in future rulemaking as we continue to examine our programs for opportunities to improve operational efficiencies and clinical efficacy. As part of the Meaningful Measures Initiative and our desire to reduce provider burden, we are working to align requirements across CMS quality programs where possible and we will consider ways to align the requirements for QIP, DFR, DFC, the Five Star Program, and Core Survey in future years.

In addition, we would like to clarify that the ESRD QIP and the Five Star Program have different objectives. The purpose of the ESRD QIP is to assign a payment penalty to facilities that do not meet national performance standards on quality measures. The purpose of Five Star Program is to provide patients with an easy way to assess quality of care, so they can make health care decisions or learn about their current dialysis facility. Analysis has shown that using

the payment reduction categories developed for the QIP as a basis for assigning Star Ratings would result in over 80 percent of facilities receiving four or five stars. This would render the Five Star Program inadequate for being able to determine the differences between facilities and allowing patients to make informed choices about their health care. The ESRD QIP is designed to reduce Medicare payments to penalize facilities that do not meet national performance standards on quality measures. Because the national performance standards are set at the median performance level from a previous time period and national performance on quality measures has typically been stable or improving over time, the majority of facilities have historically tended to meet or exceed those standards in the aggregate and have not received receive a payment reduction. We believe, however, that a 5-star rating should indicate excellence. Awarding the highest star rating to facilities based solely on where their performance for a program year falls relative to the minimum total performance score used in the ESRD QIP would not allow patients to discern the difference between facilities and would not appropriately distinguish those facilities that are providing excellent care.

Comment: One commenter agreed that our VBP programs should assess those core issues that are most critical to providing high-quality care and restated its long support for a smaller QIP measure set. Another commenter appreciated our development of the Meaningful Measures objectives and quality priorities and expressed its agreement with the application of those priorities to the QIP. The commenter also appreciated the Initiative's call for alignment across programs, noting that dialysis patients see multiple health care providers and are frequently hospitalized. A third commenter was supportive of our goal to align the QIP more closely with the Meaningful Measures Initiative, and also stated its support for our efforts to account for social risk factors in the ESRD QIP. Another commenter expressed support for

CMS's evaluation of each QIP measure in the context of improving outcomes and reducing burden.

Response: We thank the commenters for their support.

Comment: A commenter supported our work on the Meaningful Measures Initiative and suggested that the catheter > 90 days measure is the most meaningful measure in the ESRQ QIP measure set because long-term catheter use is associated with poorer clinical outcomes.

Response: We thank the commenter for its support and feedback. We believe that all of the measures included in the QIP are meaningful.

Comment: A commenter supported our prioritization of regulatory reform and burden reduction, including through Meaningful Measures. The commenter supported the use of fewer, more meaningful measures in QIP and other programs and appreciated CMS's efforts to incorporate these concepts in its proposed policies.

Response: We thank the commenter for its support.

Comment: One commenter explained that development of a patient-reported outcome measure for dialysis is one of its priorities and suggested that it would be a worthwhile investment for CMS to explore the topic further.

Response: We thank the commenter for this suggestion and agree that patient reported outcomes are important to examining quality of care. We will consider the feasibility of developing such a measure along with our other quality measure development priorities.

Comment: One commenter explained that it did not believe that measures of Transfusion Ratios, Mortality, Hospitalizations/Readmissions, Pain Management, or Transplant Access are appropriate for the QIP because the outcomes assessed by measures on those topics are largely not within the control of facilities. However, the commenter acknowledged that the Meaningful

Measures Initiative emphasizes the inclusion of measures covering significant outcomes, and that the avoidance of hospitalizations and mortality are significant outcomes. The commenter also acknowledged that including measures of hospitalizations and mortality is consistent with the Meaningful Measures Initiative, despite facilities' lack of control over those outcomes.

Response: We thank the commenter for this feedback. However, we continue to believe that shared responsibility for patients' health is an important feature of the ESRD QIP's quality measure set, and we therefore do not agree that these measures are inappropriate for the Program. We note that we have previously adopted measures that incorporate shared responsibility for patients' health across care settings, including the Standardized Hospitalization Ratio (SHR) and Standardized Readmission Ratio (SRR) measures. Though dialysis facilities may not have total control over patients' hospitalizations or readmissions, we have adopted those measures to highlight the shared responsibility that providers and suppliers have for ensuring that their patients remain healthy, which is an important clinical goal. We are continuing to build on this belief by adopting a measure of transplant waitlisting (discussed in more detail in section IV.C.1.a. of this final rule), which focuses on the responsibility shared by dialysis facilities and transplant centers for patient education about transplant options and maintaining patients' health status so that they are suitable for waitlisting. We view our efforts to improve health care quality through the adoption of cross-cutting quality measures as necessary to ensure that providers of all types have strong incentives to ensure their patients' continued health.

As we noted with respect to the SRR measures in the CY 2015 ESRD PPS final rule (79 FR 66177), while the specific causes of readmissions are multifactorial, our analyses supported the view that the dialysis facility exerts an influence on readmissions roughly equivalent to that exerted by the discharging acute care hospital. We continue to believe that the care coordination

required for numerous ESRD QIP measures requires interaction between multiple care providers, and that quality measures spanning those providers' care will necessarily incorporate shared responsibility for improved clinical outcomes.

Comment: One commenter asked that we focus the QIP's measure set on dialysis adequacy, safety/bloodstream infections (BSIs), depression management, medication management, in-center hemodialysis consumer assessment of healthcare providers and systems (ICH CAHPS), and patient-reported outcomes, and suggested that we reduce the Program's measure set to ensure that facilities focus on those clinical topics.

Response: We thank the commenter for this feedback. We proposed to reduce the ESRD QIP's measure set specifically to ensure that facilities focus on the most relevant clinical topics. However, we do not believe that the subset of topics identified by the commenter represents the fullest possible picture of care quality in dialysis facilities.

We appreciate commenters' feedback on the Meaningful Measures Initiative and its application to the ESRD QIP.

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.⁹ 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 VBP programs.¹⁰ 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 measures.¹¹ 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

⁹ 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.

¹⁰ 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-medicare-value-based-purchasing-programs>.

¹¹ Available at: http://www.qualityforum.org/SES_Trial_Period.aspx.

(SES) trial,¹² 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

¹² Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357>.

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 VBP 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.

The comments on social risk factors in the ESRD QIP, as well as our responses to those comments, are set forth below.

Comment: Some commenters appreciated our exploration of social risk factor adjustments and reiterated their support for evaluating social risk factors' impact on measuring dialysis facility performance. Commenters suggested that stratifying performance reporting for each dialysis facility by social risk factors known to influence measure performance may help illuminate outcomes disparities in dialysis facilities. Commenters also recommended that we provide support through quality improvement activities to facilities with lower quality performance and high proportions of patients with social risk factors, potentially through the ESRD Networks. However, commenters recommended against adopting any social risk factor adjustment due to the risk of masking poor performance and because they believe that risk adjustment may discourage additional improvement efforts.

Response: We thank the commenters for their support and will take their recommendations on stratifying performance under advisement. We agree with the commenters'

recommendation about providing support to dialysis facilities through quality improvement activities, such as promoting best practices for performance on ESRD QIP quality measures, and we will continue to do so to the greatest extent feasible. We also share the commenters' concern about masking poor performance rates via social risk factors adjustment and will continue to consider our options on this topic.

Comment: One commenter recommended assessing four measures for sociodemographic status (SDS) risk factors regardless of whether they are expressed as a rate or ratio: SRR, standardized transfusion ratio (STrR), standardized mortality ratio, and SHR. The commenter stated that evidence shows that patient-level SDS factors affect performance on these measures in other settings.

Response: We thank the commenter for these specific suggestions and will continue to consider our options on this topic.

Comment: One commenter suggested assessing whether a patient's insurance status at the start of his or her dialysis treatment should be applied to the arteriovenous fistula (AV fistula) clinical measure and the catheter > 90 days clinical measure. The commenter noted that patients who are uninsured when their dialysis treatment begins may have had trouble obtaining appropriate pre-dialysis care from a nephrologist. The commenter further noted that while the QIP makes some allowances for the care that dialysis patients initially receive, additional review of insurance status is appropriate.

Response: We thank the commenter for this suggestion and will consider it as we continue to examine this issue.

Comment: One commenter was concerned about the possibility that facilities may be discouraged from accepting patients with social risk factors if measures are not risk-adjusted to

account for such factors. The commenter was also concerned that facilities could be discouraged from opening or maintaining service in areas where patients with social risk factors reside and suggested that we consider a reward-based incentive for facilities that improve outcomes in populations with social risk factors.

Response: We thank the commenter for this feedback and will consider whether any of its suggestions are feasible and within the scope of our statutory authority as we further examine whether social risk factors should be accounted for in the ESRD QIP. We do not agree that incorporating social risk factors into the Program will discourage facilities from accepting patients who have those factors. We are committed to ensuring that the interests of consumers are put first and we expect providers to do the same. We encourage the commenter to contact the U.S. Department of Health and Human Services, Office for Civil Rights to submit a formal complaint if it believes that dialysis patients are being discriminated against.

Comment: A commenter requested that we consider additional social risk factors for pediatric patients, including race, ethnicity, insurance status, and other socioeconomic factors, as well as school attendance, academic performance, and peer interactions. The commenter also suggested that we consider additional factors for parents and other primary caregivers, including employment status, financial burden of a chronically ill dependent child, and levels of fatigue and caregiver burn-out. The commenter also noted that pediatric patients may face disparities in access to care when they are displaced by natural disasters.

Response: We thank the commenter for these suggestions and will take them into account as we continue analyzing whether social risk factors should be accounted for in the ESRD QIP.

Comment: A commenter suggested studying the following SDS factors to determine

whether and to what extent they affect patient outcomes: income (for example, dual eligibility/low-income subsidy), race and ethnicity, insurance status at dialysis initiation, and geographic area of residence. The commenter offered to work with CMS to identify additional SDS factors that affect patient outcomes. The commenter also suggested that CMS use its dual eligibility/low-income subsidy data and geographic area of residence data as additional data points for social risk factors adjustment. The commenter also recommended using patient self-reporting to collect data for race/ethnicity. Another commenter suggested that we consider developing a temporary risk-adjustment policy based on our experience with risk adjustment for dual-eligible patients in the Medicare Advantage Program.

Response: We thank the commenters for these suggestions and will take them into account as we continue to examine this issue. We also note that we will continue to welcome input from all stakeholders on this important topic.

Comment: A commenter expressed support for our efforts to assess and account for social risk factors in the QIP through adjusters and other mechanisms. The commenter agreed that providers and suppliers should be assessed fairly, without masking potential disparities or creating disincentives to care for more medically complex patients.

Response: We thank the commenter for its feedback.

Comment: A commenter supported the elimination of health disparities and noted that health disparities are particularly pronounced in the kidney patient population, where African Americans are four times as likely and Latino Americans are twice as likely to have kidney disease. The commenter encouraged CMS to revisit the commenter's recommendations related to improving health equity that were submitted in response to the CY 2018 ESRD PPS proposed rule.

Response: We thank the commenter for its suggestions and recommendations submitted in response to the CY 2018 ESRD PPS proposed rule, to which we responded in the CY 2018 ESRD PPS final rule (82 FR 50759). In that final rule, we stated that we intend to consider all suggestions as we continue to assess each measure and the overall Program. We will continue to take these suggestions into account as we continue to examine health disparities and health equity.

Comment: A commenter suggested not applying SDS factors to three measures: the Kt/V Dialysis Adequacy Comprehensive clinical measure, the Hypercalcemia clinical measure, and the New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure. The commenter believed that no evidence shows that SDS factors affect performance on these measures. Another commenter suggested not adjusting the NHSN BSI in Hemodialysis Patients clinical measure for SDS factors. Another commenter suggested not adjusting the QIP's reporting measures for SDS factors. The commenter stated that the purpose of reporting measures is to assess whether the facility has reported the required data, rather than assessing patient outcomes.

Another commenter acknowledged the importance of trying to account for social risk factors through risk adjustment in the Program but expressed concern that those adjustments could have unintended consequences on the quality of care received in dialysis facilities. The commenter recommended that CMS ensure that patients continue receiving the highest standards of care and acknowledge the challenges associated with capturing data for Program measures under the current systems.

Response: We thank the commenters for these suggestions and will take them into account as we continue analyzing the social risk factors topic.

Comment: A commenter suggested that we review and make publicly available the data needed to determine the effect of SDS factors on the ICH CAHPS Survey clinical measure. The commenter believed that the effect of SDS factors on the survey's response rate is unknown. Another commenter was uncertain about the effects of SDS adjustment on the ICH CAHPS Survey and requested that we study the issue further.

Response: We thank the commenters for this feedback. Education is included as a case mix adjuster for the ICH CAHPS Survey. We are currently examining the effects of other social risk factors on ICH CAHPS Survey responses and will provide as much information as possible to the public as these results are finalized.

Comment: A commenter offered to assist CMS in assessing the effects of SDS factors, such as geography, biological factors, and demographic factors, on transplantation measures. The commenter believed that factors such as regional differences may affect transplantation access and eligibility, and therefore may affect waitlist placement.

Response: We always welcome feedback from all stakeholders on these and other issues related to the ESRD QIP.

Comment: A commenter recommended that we continue studying ESRD QIP measures for appropriate social risk factors adjustment. The commenter specifically suggested that we consider such adjustments for the SRR, STrR, and SHR measures, as well as the vascular access type (VAT) measures (for insurance status at time of dialysis initiation). However, the commenter recommended against adjustment for the Kt/V Dialysis, Hypercalcemia, and NHSN BSI clinical measures, and the reporting measures. The commenter also requested that we study the effects of SDS factors on measures of transplantation.

Response: We thank the commenter for this feedback and will take it into account as we

continue to examine this issue.

Comment: One commenter questioned the ASPE report's conclusion that dual-eligible status is the strongest predictor of disparate clinical outcomes, noting that many patients with dual Medicare and Medicaid coverage have access to social services that patients without Medicaid coverage do not. The commenter suggested that CMS evaluate additional data points on social risk factors such as mental health status and income ranges.

Response: We thank the commenter for this feedback and acknowledge that there are other critical social risk factors that should be considered. However, as noted in the ASPE report, our analyses are limited to the social risk factors available in Medicare claims data. We will continue to examine other social determinants of health as additional social risk factor data are made available.

3. Updated Regulation Text for the ESRD QIP

In the CY 2019 ESRD PPS proposed rule (83 FR 34336), we proposed 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. We stated that codification of these requirements would make it easier for the public to locate these requirements, and that 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.

We also stated that 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 invited public comments on the proposed regulation text.

The comments and our responses to our regulation text proposals are set forth below.

Comment: One commenter suggested including a reference in the performance standards definition to the 50th percentile of national performance during the baseline period for the performance year, similar to its inclusion in the attainment threshold and benchmark definitions.

Response: We thank the commenter for the suggestion. However, we disagree with the commenter's suggestion to include a reference in the performance standards definition to the 50th percentile of national performance during the baseline period for the performance year. As initially defined in the PY 2012 ESRD QIP final rule (76 FR 629 through 631), the performance standards term applies more broadly to levels of achievement and improvement and is not a specific reference to the 50th percentile of national performance.

Comment: One commenter suggested that CMS revise the clinical and reporting measure definitions proposed to be codified at § 413.178(a)(4) and (a)(13), respectively, and reclassify the QIP's measures using terms more widely used in the community-- structural, process, outcomes, access, and efficiency--in future rulemaking. The commenter expressed concern that the

proposed definitions could be manipulated and suggested defining outcome measures as clinical measures and structural measures as reporting measures. The commenter also suggested clarifying in the scoring section that paragraphs (d)(1)(i) through (iii) describe the scoring for clinical measures and that paragraph (d)(1)(iv) describes the scoring for reporting measures.

Response: We disagree with the commenter's suggestion to reclassify the Program's measures because the Program's current measure classification—reporting and clinical—represents the way in which the Program measures are scored and are Program specific. The commenters suggested classification system—structural, process, outcome, access, and efficiency—describe individual measure goals in terms of quality assessment.

We also disagree with the commenter's suggestion to add clarifying language to the scoring section to differentiate between scoring for clinical measures and reporting measures; each paragraph in § 413.178(d)(1) specifies whether the scoring methodology described in that paragraph applies to clinical measures or reporting measures.

Comment: A commenter expressed concern that that the proposed language to be codified at § 413.178(c) deviates from the statutory text at 42 U.S.C. 1395rr(h)(2). The commenter also expressed concern that CMS has not referenced the patient satisfaction provision in the language proposed to be codified. The commenter also expressed concern that CMS has not proposed to codify the requirement that the QIP use measures that are NQF-endorsed unless the exception applies. The commenter suggested that the regulatory text state that if NQF has reviewed but not endorsed a measure, then the exception does not apply.

Response: We thank the commenter for this feedback. We have revised the regulation text in § 413.178(c)(3) to reflect the statutory requirement to include a patient satisfaction measure to the extent feasible. However, we disagree that the regulatory text should state that if

the NQF has reviewed but not endorsed a measure, then the exception that allows us to adopt a measure that has not been endorsed by the NQF should not apply. Section 1881(h)(2)(B) of the Act does not limit us to using only NQF-endorsed measures in the Program. Rather, that section allows us, in the case of a specified area or medical topic determined appropriate for which a feasible and practical measure has not been endorsed, to specify a measure that is not so endorsed as long as we give due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We do not believe it would be in the best interest of the Program to limit our ability to adopt measures that are not NQF-endorsed if, for example, they address significant clinical topics (as outlined by the priorities we described under the Meaningful Measures Initiative in section IV.B.1 of this final rule), or if they otherwise present significant opportunities for care quality improvement in dialysis facilities.

Comment: A commenter raised concerns that the proposed regulatory text that would be codified at § 413.178(d) does not reflect current scoring policies. The commenter suggested removing 0 as an achievement score option at paragraph (d)(i), noting that the FY 2019 Program details show that a facility with a measure performance below the achievement threshold receive an achievement score of 0 points, a facility with a measure performance that falls within the range receives an achievement score of 1 to 9 points, and a facility with a measure performance at or above the benchmark receives an achievement score of 10 points. The commenter also suggested clarifying at paragraph (d)(ii) that 0 points is provided as an option for scoring achievement for facilities whose performance falls below their comparison rate. The commenter also raised concerns that the references in paragraph (d)(iv) are very general and that the Program details recommend including reporting measure requirements in the rule. The commenter suggested that the regulatory text refer the reader to the location of the specific

requirements if the Program details cross-reference remains.

Response: We thank the commenter for this feedback. However, we would like to clarify that the proposed regulation text at § 413.178(d)(1)(i) states that we will award between 1 and 9 points for achievement 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. Facilities whose performance on a measure does not meet or exceed the achievement threshold for that measure will not be awarded between 1 and 9 points; they will instead be awarded 0 points for that measure, because their performance does not fall within the specified range.

We would also like to clarify that the language that we proposed at § 413.178(d)(1)(ii) is intended to capture situations where a facility's performance on a measure does not improve from the comparison period. By stating that we will award between 0 and 9 points for improvement, we believe we have appropriately captured that possibility.

Comment: A commenter expressed concern about the regulatory text proposing to codify the recent changes to the performance score certificate (proposed § 413.178(e)(3)). The commenter raised concerns about including only the total performance score (TPS) on the revised performance score certificate (PSC). The commenter stated that the DFC website--where detailed information is available--needs improvement, that many patients may not have internet access, and past inclusion of more detailed information on the PSC has created an expectation among patients that they can view detailed information on the PSC. The commenter suggested that the PSC is difficult to read because QIP does not use a parsimonious set of measures.

Response: We thank the commenter for this feedback. We finalized changes to the PSC in the CY 2018 ESRD PPS final rule (82 FR 50759 through 50760), and we did not address this

topic in the CY 2019 ESRD PPS proposed rule. However, we will take this feedback into consideration in future years.

Final Rule Action: After consideration of the public comments we received, we are finalizing our proposed regulation text with revisions to more clearly reflect previously finalized ESRD QIP policies. Specifically, we are revising the regulation text at § 413.178(c) to more clearly incorporate the requirement at section 1881(h)(2)(A) of the Act that the ESRD QIP measure set include, to the extent feasible, a measure (or measures) of patient satisfaction. We are also revising our proposed regulations text to include two new additional paragraphs at § 413.178(d)(1)(ii) and (d)(1)(iv) to clarify that we will award zero points for achievement on a clinical measure to each facility whose performance falls below the achievement threshold for that measure, and that we will award zero points for improvement on a clinical measure to each facility whose performance falls below the improvement threshold for that measure. We are renumbering the provisions in the proposed paragraph (d)(1) to accommodate these new paragraphs.

Update to Requirements Beginning with the PY 2021 ESRD QIP

1. Updates to the PY 2021 Measure Set

In the CY 2019 ESRD PPS proposed rule (83 FR 34336-34340), we proposed 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 VBP programs, stated that we would now refer to these criteria as factors. We also proposed 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 final 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	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
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

Comment: Numerous commenters provided feedback on various aspects of measures

that are continuing in PY 2021. These comments included recommendations to keep or remove continuing measures from the Program, recommendations to modify continuing measures (for example, by revising their exclusions), and recommendations to reduce the provider burden associated with continuing measures (for example, by changing the administration of the ICH CAHPS Survey).

Response: We thank the commenters for their feedback. We note that these comments are not responsive to a proposal included in the CY 2019 ESRD PPS proposed rule, and therefore, are considered beyond the scope of the proposed rule. We refer readers to the CY 2018 ESRD PPS final rule (82 FR 50767 through 50769), the CY 2017 ESRD PPS final rule (81 FR 77898 through 77906), and the CY 2016 ESRD PPS final rule (80 FR 69052 through 69053) for public comments on measures that we have previously adopted for the ESRD QIP and our responses.

a. Refinement and Update to 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 stated in the CY 2019 ESRD PPS proposed rule (83 FR 34338) that we would now refer to these criteria as “factors” rather than “criteria.” We also proposed 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 proposed to combine current Factors 4 and 5 (proposed new Factor 4), and we proposed to adjust the numbering of subsequent factors to account for this change. We also proposed 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. The 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 stated that we believe these proposed updates would better ensure that we use a consistent approach across our quality reporting and VBP 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 stated that 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 proposed to apply these factors on a case-by-case basis.

We invited public comment on these proposals. The comments and our responses to

those comments are set forth below.

Comment: A commenter supported measure removal factors 1 through 8. The commenter urged CMS to include stakeholders in decisions related to factor 8 removal.

Response: We thank the commenter for its support and note that we always welcome feedback from all stakeholders regarding our policies for the ESRD QIP. We also note that we would propose to remove any measures under Factor 8 through notice and comment rulemaking, thereby allowing opportunities for stakeholders to participate in decisions related to that factor.

Comment: A commenter expressed support for Factors 1, 2, 3, 6, 7, and 8 as well as the proposed list of costs that CMS would consider for Factor 8. The commenter suggested that Factors 4 and 5 be revised to state that "become available" means that the replacement has been tested for patients with ESRD and at the dialysis facility level.

Response: We thank the commenter for its support. Our intention is to adopt measures that have been tested for patients with ESRD and at the dialysis facility level. This policy is consistent with our policy to only adopt measures that are reliable and valid. We note that we can remove a measure without a replacement using other measure removal factors.

Comment: A commenter supported our adjustments to the measure removal factors. Two commenters encouraged us to consider adding an additional factor for measures that do not meet NQF's scientifically-accepted measure evaluation and testing criteria. One of those commenters noted that the QIP includes several measures that NQF has rejected and suggested that their inclusion is inconsistent with our statutory authority.

Response: We thank the commenter for its support. Although we acknowledge that there are some QIP measures that are not currently NQF-endorsed, we note that we have statutory discretion to include such measures in the QIP where there is no feasible or practical

NQF-endorsed measure on a topic that we have determined appropriate as long as we give due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: A commenter stated general agreement with the proposed measure removal factors and expressed appreciation that they align with factors in other programs. The commenter also suggested that we continue to require CROWNWeb reporting of measures that have been removed from the ESRD QIP due to topped-out status for at least 3 years in order to monitor unintended changes in performance.

Response: We appreciate the commenter's feedback. We agree that we should strive to prevent unintended consequences related to the removal of a QIP measure, and we currently monitor for such consequences through our usual monitoring and evaluation activities.

Comment: A commenter supported our proposal to add additional measure removal factors to the ESRD QIP.

Response: We thank the commenter for this support.

Comment: A commenter expressed strong support for including the new measure removal factors and agreed that topped out measures should be removed. However, the commenter believed that the current definition of topped-out is too stringent and not patient centered. The commenter suggested revising CMS's mathematical definition to allow for a measure that is clinically topped out to remain in the QIP if the removal of that measure would discourage facilities from incorporating patient preference into their care decisions.

Response: We thank the commenter for its support. We also that in the CY 2015 ESRD PPS final rule, we 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). We believe that this policy provides us sufficient flexibility to continue using a measure that might be topped-out according to our statistical criteria but otherwise addresses an important aspect of clinical quality for the ESRD population.

Comment: A commenter expressed concern with the proposal that would allow CMS to retain a measure even if the measure otherwise qualified for removal under one of the proposed measure removal factors. The commenter believed that the purpose of the measure removal factors is to provide predictability and consistency among programs, and that retaining a measure that satisfies one of the measure removal factors would undermine those goals.

Response: We understand the commenter's concern. However, we may have strong justification for continuing to use a measure that satisfies one of the measure removal factors and that this justification may outweigh removing the measure from QIP. We also note that unless a measure needed to be immediately removed for patient safety reasons, we intend to continue making measure removal decisions for the ESRD QIP through rulemaking, and we believe that this process provides sufficient predictability for facilities and consistency among our programs.

Comment: A commenter recommended that CMS utilize a consistent numbering sequence for the measure removal factors across all of its programs and that all of the measure removal factors be standardized. The commenter stated that ESRD QIP, Hospital VBP, Inpatient Quality Reporting, and PPS-Exempt Cancer Hospital Quality Reporting; and Inpatient Psychiatric Facilities Quality Reporting Programs have a removal factor (measure is not feasible to implement as specified) not included in the other programs. The commenter believed that inconsistent numbering and removal factors across programs may contribute to confusion and add to the burden of managing and reviewing rules.

Response: We thank the commenter for this feedback. Our proposals in the CY 2019 ESRD PPS proposed rule were intended to conceptually align our measure removal factors across our programs. While we have attempted to align the numbering and language of the measure removal factors across programs, we acknowledge that the ESRD QIP's measure removal factors have minor, non-substantive differences in language and numbering when compared to HIQR, HVBP, PCHQR, and IPFQR.

Final Rule Action: After considering public comments, we are finalizing the updates to the existing measure removal factors as proposed.

b. New Measure Removal Factor

In the CY 2019 ESRD QIP proposed rule (83 FR 34338 through 34339), we proposed 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 the CY 2019 ESRD PPS proposed rule (83 FR 34338 through 34339), 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.

We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34338 through 34339) that 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, we stated our belief that 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 proposed that we would remove measures based on this factor on a case-by-case basis. We stated that 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. We stated that 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 invited 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.

Comment: A commenter urged us to consider that the benefits of a measure's continued use in the ESRD QIP may not be the same for the agency, providers, and patients when assessing whether a measure's costs outweigh the benefits of its continued use in the Program. The commenter stated that some facilities struggle to participate fully in the Program because the Program does not include pediatric-specific measures and pediatric dialysis patients are excluded from the calculation of most QIP measures. The commenter stated that facilities that furnish dialysis mainly to pediatric patients might benefit from the retention of measures that impose costs to other stakeholders because the retention of those measures would enlarge the overall number of measures that these facilities can report.

Response: We thank the commenter for this suggestion, and we agree. We intend to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare purchasers, and patient and family advocates. Because for each measure the relative benefits to each stakeholder may vary, we believe that the benefits to be evaluated

for each measure are specific to the measure and the original rationale for including the measure in the Program.

We also understand that while a measure's use in the ESRD QIP may benefit many entities, the primary benefit is to patients and caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted and are illustrated through the domains of the Meaningful Measures Initiative. When the costs associated with a measure outweigh the evidence supporting the benefits to patients with the continued use of a measure in the ESRD QIP, we believe it may be appropriate to remove the measure from the Program.

Final Rule Action: After considering public comments, we are finalizing Measure Removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the Program, as proposed, for use in the ESRP QIP, beginning with PY 2021.

c. Removal of Four Reporting Measures

As we discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34339), we have undertaken efforts to review the existing ESRD QIP measure set in the context of the Meaningful Measures Initiative. Based on that analysis and our evaluation of the Program's measures, we proposed to remove four measures previously adopted for the ESRD QIP, starting with PY 2021. We stated that 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 proposed to remove from the ESRD QIP measure set are:

- Healthcare Personnel Influenza Vaccination.

- Pain Assessment and Follow-Up.
- Anemia Management.
- Serum Phosphorus.

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 stated in the CY 2019 ESRD PPS proposed rule (83 FR 34339) that we continue to believe that the Healthcare Personnel Influenza Vaccination measure provides the benefit of protecting patients against influenza. However, we stated that 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. We stated that 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 proposed 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).

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 stated in the CY 2019 ESRD PPS proposed rule (83 FR 34339) that 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. We stated that 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 proposed 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).

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, we stated that 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.

In the CY 2019 ESRD PPS proposed rule (83 FR 34339), we stated that 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 therefore proposed 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).

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.

In the CY 2019 ESRD PPS proposed rule (83 FR 34340), we stated that 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 stated in the CY 2019 ESRD PPS proposed rule that 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 proposed 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 invited comments on these proposals. We also stated in the CY 2019 ESRD PPS proposed rule that we did not propose any changes to the PY 2021 performance period or performance standards, and we referred readers to the CY 2018 ESRD PPS final rule (82 FR 50778 through 50779) for a discussion of those policies.

Comment: One commenter supported our proposal to remove the HCP Influenza Vaccination, Pain Assessment and Follow-up, and Anemia Management Reporting measures.

Response: We thank the commenter for its support for removing the HCP Influenza Vaccination, Pain Assessment and Follow-up, and Anemia Management Reporting Measures.

Comment: Some commenters suggested keeping the Serum Phosphorus measure in the QIP and removing the Hypercalcemia measure. One commenter noted that the NQF has concluded that the hypercalcemia measure is topped out and that there is agreement among nephrologists that the Hypercalcemia measure is not the best measure to affect patient outcomes. Another commenter stated that physicians and nurses use the Serum Phosphorus measure in

clinical decision-making and that the Serum Phosphorus measure meets PAMA requirements. Another commenter believed that Serum Phosphorus is the only measure that meets PAMA requirements for an NQF-endorsed quality measure of conditions treated with oral-only medications. Another commenter noted that the Hypercalcemia measure is topped out and that dialysis facilities may focus less on other, more important clinical topics to avoid QIP penalties. Another commenter disagreed with our assessment that the Hypercalcemia clinical measure is a better measure than the Serum Phosphorus reporting measure, particularly for the pediatric population. The commenter stated that it takes a significant amount of time and clinical effort to control phosphorus levels in pediatric patients and suggested that the Serum Phosphorus reporting measure is particularly meaningful for that population.

Another commenter recommended that CMS remove the Hypercalcemia measure instead of the Serum Phosphorus measure. The commenter also suggested that the statutory requirement to include a mineral metabolism measure in the ESRD QIP no longer applies to hypercalcemia drugs with the launch of the IV calcimimetic. In addition, the commenter suggested that the Hypercalcemia measure is not clinically useful, is topped out, and discourages the home dialysis modality due to its reliance on monthly labs that require the patient to visit the facility.

Response: As we described in the CY 2019 ESRD PPS proposed rule (83 FR 34340), in 2017, the NQF re-endorsed the Hypercalcemia measure and its focus on clinical factors that are more directly under the facility's control. We noted further that the Hypercalcemia clinical measure is more focused on outcomes, which we believe should be emphasized more heavily in the ESRD QIP than reporting measures. However, we will continue examining the effects of the ESRD QIP's measures on different patient populations, including pediatric patients.

We note, however, that we have not adopted an IV calcimimetic measure in the ESRD

QIP, and we therefore, do not agree that its launch means that the statutory requirement that we include measures of mineral metabolism in the ESRD QIP no longer applies.

We would also like to clarify that we have not concluded that the Hypercalcemia measure is topped out, and we will continue to assess the ESRD QIP to ensure that dialysis patients are not discouraged from pursuing treatment via their preferred modalities.

Comment: Commenters supported our proposal to remove four reporting measures from the Program. One commenter noted that the proposal takes a much-needed step towards creating a smaller, more patient-centered measure set. Another commenter suggested that we consider adding health care personnel influenza vaccinations to Medicare's conditions for coverage for ESRD facilities. One commenter requested clarification as to whether facility reporting on the health care personnel influenza vaccination measure would be discontinued beginning October 1, 2018--the start of the PY 2021 period of performance.

Response: We thank the commenters for their feedback and support, and we will consider whether we should add health care personnel influenza vaccinations to our conditions for coverage in the future. We intend to continue monitoring outcomes associated with influenza in the dialysis patient population. We would like to clarify that facilities can discontinue data collection on the HCP influenza vaccination measure beginning with October 1, 2018 dates of service and will not be required to submit vaccination reports in May 2019 for PY 2021.

We would also like to clarify that the Healthcare Personnel Influenza Vaccination reporting measure is evaluated on the basis of facility reporting to the NHSN, not on healthcare personnel influenza vaccination rates, and that the consistently high facility performance on the measure indicates that facility reporting, not influenza vaccination rates of facility staff, is a widespread practice and that there is little room for improvement on this reporting measure.

Comment: Commenters expressed support for the proposed removal of the Pain Assessment and Follow-Up reporting measure. One commenter stated that performance on the measure is uniformly high, and another commenter agreed that if meaningful distinctions among facilities for a specific measure cannot be made, then that measure should be removed from QIP. Another commenter stated that these types of measures may contribute to the opioid epidemic and that the pain management measure was not designed for dialysis patients. Another commenter believed that the standardized pain measurement tool is expensive and burdensome for facility staff and data entry coordinators.

Response: We thank the commenters for their support.

Comment: One commenter did not have any objection to our proposal to remove the Serum Phosphorus and Pain Assessment measures from the Program. Another commenter expressed support for removing the Healthcare Personnel Influenza Vaccination reporting measure, stating that it does not align with current clinical practice. Other commenters supported our proposal to remove HCP Influenza Vaccination, Pain Assessment and Follow-Up, and Anemia Management reporting measures.

Response: We thank the commenters for their support of the measure removals. We note that the CDC and the Advisory Committee on Immunization Practices recommend annual seasonal influenza vaccination for all healthcare personnel, including those working in dialysis facilities. However, the ESRD QIP does not include a Healthcare Personnel Influenza Vaccination clinical measure that would evaluate facility performance on the basis of the proportion of ESRD healthcare personnel who undergo vaccination. The Program's Healthcare Personnel Influenza Vaccination measure proposed for removal is a reporting measure that assesses facilities' reporting of healthcare personnel influenza vaccination data to the NHSN

system. Since facility reporting on the measure is high and there is little room for improvement, we proposed to remove the measure from the Program.

Comment: Commenter supported the removal of the Healthcare Personnel Influenza Vaccination reporting measure, suggesting that the data suggests facility compliance with the measure is close to 100 percent and the measure is no longer necessary for inclusion in QIP.

Response: We thank the commenter for this feedback and support.

Comment: Commenter generally supported our proposal to remove four reporting measures from the Program but expressed concern about the removal of the influenza vaccination measure. The commenter believed that the measure helps ensure that a healthy workforce furnishes services to ESRD patients, and worried that the removal of the measure will result in fewer employees becoming vaccinated.

Response: We thank the commenter for this support. As we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34339), 98 percent of ESRD facilities received the highest possible score on the influenza vaccination measure, indicating that almost all ESRD facilities were reporting influenza vaccination of healthcare personnel. CDC and the Advisory Committee on Immunization Practices (ACIP) recommends that all healthcare personnel (HCP) and persons in training for healthcare professions should be vaccinated annually against influenza, given that HCP vaccination has been associated with reduced work absenteeism and fewer deaths among elderly patients. We and CDC will continue monitoring the effects of the measure's removal and the distal outcomes associated with influenza in the dialysis patient population, and will work to ensure that ESRD facilities continue to maintain the healthiest possible workforce. CDC also encourages ESRD facilities to continue to report this measure as part of their quality improvement programs.

Comment: A commenter supported the removal of the Serum Phosphorus reporting measure. However, the same commenter raised concerns that removing this measure from QIP will not reduce facility burden, as it is still a required field in CROWNWeb and CMS would still collect phosphorus values for use in DFC/DFR reports.

Response: Our goal is to streamline the QIP and implement a parsimonious, effective quality measure set. To that end, we are removing the Serum Phosphorus measure from the QIP because we have determined that the Hypercalcemia measure is a better measure of bone mineral metabolism compared to the Serum Phosphorus measure and given NQF's recent re-endorsement of the Hypercalcemia measure. We continue to believe that this removal reduces the burden associated with the ESRD QIP. However, we will examine the other burdens associated with the measure that the commenter highlighted and will consider whether we should remove any of those requirements in service of reducing facilities' reporting burden further.

Comment: Commenter was generally supportive of reducing the size of the ESRD QIP measure set but expressed concern about the proposed removal of the HCP Influenza Vaccination reporting measure. The commenter agreed with our assessment that performance on the measure is likely high across the industry and acknowledged the comparatively high burden associated with the measure but noted that the measure is also required by CDC's NHSN, meaning that its removal from the QIP wouldn't relieve facilities of the responsibility to report on it. Commenter encouraged us to work with CDC to align reporting requirements. Another commenter stated that the HCP Influenza Vaccination reporting measure is still meaningful, and its reporting burden is not particularly burdensome.

Response: As noted above, our goal is to streamline the QIP and implement a parsimonious, effective quality measure set. We also note that the CDC continues to encourage

vaccination reporting, and that the CDC and the Advisory Committee on Immunization Practices (ACIP) recommend that all healthcare personnel (HCP) be vaccinated annually against influenza.

Comment: A commenter was concerned that the dates of vaccine availability for the HCP Influenza Vaccination measure do not coincide with the measure's reporting dates. The commenter encouraged us to modify the measure to align with CDC's immunization guidelines. Another commenter recommended that we adjust the reporting dates for the HCP Influenza vaccination to allow administrations beginning October 1 or when the vaccine becomes available.

Response: We thank the commenter for their feedback. Since we are finalizing our proposal to remove the Healthcare Personnel Influenza Vaccination measure from QIP, facilities will not be required to collect vaccination data beginning October 1, 2018—which would have been the beginning of the PY 2021 period of performance for that measure.

Comment: Commenters were concerned about our proposal to remove the HCP Influenza Vaccination measure from the QIP. One commenter believed that the measure's removal will send the message that preventive health services such as immunizations are no longer a priority. That commenter noted that sustained influenza vaccination should be a top priority for workers treating ESRD patients since they are at high risk for infectious diseases and that the measure's removal would create greater inconsistency across CMS's quality programs. Another commenter believed that removing the measure may result in facilities no longer mandating that their personnel receive vaccinations.

One commenter opposed the measure's removal based on its belief that the measure supports patient outcomes. The commenter stated that high compliance should be expected because the measure was adopted recently. The commenter noted that healthcare personnel can

unintentionally expose patients to seasonal influenza if they have not been vaccinated and that patients with ESRD and acute kidney injury are often at risk for influenza due to their complex underlying comorbidities. The commenter also stated that annual influenza vaccination of healthcare personnel has been shown to reduce flu-related morbidity and mortality among health care personnel and their patients and reduce work absenteeism. The commenter also believed that a vaccinated workforce creates a safe environment for patients, their families, and employees.

Response: We agree that influenza vaccination of healthcare personnel is an important public health measure to protect both the healthcare personnel and ESRD patients against flu-related morbidity and mortality and healthcare personnel absenteeism. As we have noted previously, CDC and the Advisory Committee on Immunization Practices recommend annual seasonal influenza vaccination for all healthcare personnel, including those working in dialysis centers. However, as described above, our goal is to streamline the QIP and implement a parsimonious, effective quality measure set for dialysis facilities, and we continue to believe that the high reporting rate on the HCP Influenza Vaccination measure indicates that there is little room for facilities to improve reporting on the measure. However, we will continue to monitoring the issue to assess whether the measure's removal results in any negative unintended consequences.

Comment: A commenter encouraged us to continue requiring reporting of the Pain Assessment and Follow-up reporting measure, the Healthcare Personnel Influenza Vaccination reporting measure, and the Anemia Management reporting measure. The commenter also urged us to maintain the Serum Phosphorus measure in the QIP until a better measure of bone and mineral metabolism can be developed. The commenter believed that the Pain Assessment

measure, in particular, is important to patients and that a high performance rate on the measure does not indicate absence of a gap in addressing pain in dialysis patients. Another commenter stated that data do not support a performance measure based on hemoglobin level at this time but suggested that anemia management is still important as a reporting measure. Another commenter stated that anemia measures are helpful and may improve clinical outcomes for people in earlier stages of chronic kidney disease (CKD). The commenter recommended that we continue collecting the data for both the hemoglobin level and whether the patient received anemia treatment prior to ESRD onset. That commenter also suggested that we allow more granular anemia reporting.

Response: As we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34339 through 34340), the NQF recently re-endorsed the Hypercalcemia measure, and the Hypercalcemia measure focuses on clinical factors that are more directly under the facility's control. We therefore believe that the Hypercalcemia clinical measure is a better measure of bone mineral metabolism than the Serum Phosphorus reporting measure, and in the interest of maintaining a more parsimonious quality measure set under the ESRD QIP, as well as a quality measure set more focused on clinical outcomes, we proposed to remove Serum Phosphorus.

With respect to the Pain Assessment measure, while we understand the commenter's point that high performance rates on the measure may not indicate the absence of a gap in addressing pain in dialysis patients, we weighed high performance on the measure against the measure's reporting burden and clinical value when we proposed to remove it. We expect that dialysis facilities will continue working to ensure that their patients' pain is assessed as thoroughly as possible.

We continue to believe that Anemia Management measure should be removed from the

QIP because it is a reporting measure, is topped out, and is not consistent with FDA guidelines on the use of Erythropoietic Stimulating Agents (ESAs), because any measure focused on a specific hemoglobin level or target encourages ESA use for reasons other than symptom relief, and that action is associated with adverse cardiovascular effects.

Comment: Commenter opposed the removal of the Anemia Management measure, suggesting that its removal would not reduce burden. Commenter stated that facilities are still required to report this information on Medicare claims on a monthly basis.

Response: We thank the commenter for this feedback. Our goal is to streamline the QIP and implement a parsimonious, effective quality measure set. To that end, we are removing the Anemia Management measure from the QIP because as previously noted, our analysis of CY 2016 data indicates that ESRD facility performance on the Anemia Management reporting measure was consistently high, indicating 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. Given these findings, we believe that the measure's continued inclusion in QIP is no longer necessary. However, we agree that removing the Anemia Management reporting measure from QIP will not reduce facility burden as measured by the Program because facilities do not report the measure's data through CROWNWeb. We will examine the other burdens associated with the measure that the commenter highlighted and will consider whether we should remove any of those requirements in service of further reducing facilities' reporting burden.

Comment: Commenter cautioned that removing the Anemia Management measure may result in facilities' skimping on medications vital to anemia management, which is a critical aspect of dialysis care. The commenter believed that anemia management in general remains of

critical importance as a quality indicator.

Response: We understand the commenter's concern. We undertake a robust monitoring and evaluation effort for the ESRD QIP, and we will work to ensure that dialysis facilities do not skimp on needed medications or otherwise reduce the quality of the care they provide due to quality measure removals. In addition, the STrR measure remains in QIP, and facilities are still required to report hemoglobin levels in CROWNWeb and claims.

Comment: Commenter stated its opposition to removing the Anemia Management measure, suggesting that its removal while continuing to rely on the STrR measure raises significant concerns because the STrR measure will not accurately reflect the quality of care at dialysis facilities. Commenter stated its belief that STrR has not been a valid measure of transfusions since the implementation of the ICD-10-CM/PCS coding system and encouraged us to maintain the Anemia Management measure until we can assess the STrR measure's validity independently.

Response: We thank the commenter for its feedback. As we discuss further in a subsequent section of this final rule, we are finalizing a lower weight for the STrR measure in response to concerns raised about the measure, but we decided to retain that measure in the QIP as a way to monitor quality for anemia management.

Comment: A commenter supported the creation of a new reporting-only measure for anemia management, based on the average of 3 months of data. The commenter suggested that this measure is especially appropriate for the pediatric population, contending that, within the pediatric population, data shows that morbidity and hospitalizations rise when hemoglobin is less than 10g/dL.

Response: We thank the commenter for this feedback. We are constantly evaluating our

measures of anemia management and will consider measures that address the pediatric population in future years.

Final Rule Action: After consideration of public comments received, we are finalizing the removal of the Healthcare Personnel Influenza Vaccination reporting measure, the Pain Assessment and Follow-Up reporting measure, the Anemia Management reporting measure, and the Serum Phosphorus reporting measure beginning with the PY 2021 ESRD QIP.

2. 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. We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34340) that we did not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we did not yet have complete data from CY 2017.

Nevertheless, we stated that we could estimate these numerical values based on the most recent data available at the time we issued the CY 2019 ESRD PPS proposed rule. We have since updated those values based on more recently available data. In Table 14, we provide the estimated numerical values for all finalized PY 2021 ESRD QIP clinical measures, as shown in the CY 2019 ESRD PPS proposed rule (83 FR 34340). We also provide updated values for the clinical measures, using CY 2017 data that facilities submitted in the first part of CY 2018 in Table 15.

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, we stated that 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 proposed to continue use of this policy.

The comments and our responses regarding the estimated performance values and our proposal to continue our policies for substituting the performance standard, achievement threshold, and benchmark in appropriate cases, are set forth below.

Comment: Commenters generally supported the continued use of benchmarks, attainment and improvement standards, and payment penalty tiers in the QIP. One commenter recognized of the importance of the NHSN re-baselining process and its impact on the NHSN BSI clinical measure.

Response: We thank the commenters for their support.

Comment: Commenter requested that we consider new approaches to care, such as Transitional Care Dialysis units, when developing QIP standards, and suggested that we consider an acuity adjustment when scoring facilities in the QIP.

Response: We thank the commenter for this suggestion. At this time, we do not believe it is feasible to implement an acuity adjustment for scoring facilities in the QIP. However, as we discussed earlier in this final rule, we are continuing to consider appropriate adjustments to account for social risk factors in the ESRD QIP's measurements and in our other VBP and quality reporting programs.

Comment: Commenter called on us to consider incorporating flexibility into our performance standards to ensure that facilities failing to achieve Kt/V performance standards due to patient preferences can still perform well on the measure. The commenter suggested that treatment changes that would enable a facility to score more highly on the measure would not be desirable if those treatment changes were not consistent with the patients' preferences.

Response: We thank the commenter for their feedback. However, the methodology that we employ to performance standards reflects national performance on quality measures because we believe that setting national standards of care will drive quality improvement in this sector. We agree with the commenter that quality measurements that do not accord with the patients' preferences would not be a desirable outcome, but we believe that dialysis adequacy as measured by Kt/V remains a critically important indicator of clinical quality for all dialysis patients.

Comment: A commenter requested that CMS provide adequate notice if the achievement thresholds and benchmarks change after the final rule is published.

Response: We will make every effort to notify all stakeholders if the achievement thresholds and benchmarks change after we publish the final rule. Potential notification options include (but are not limited to) correction notices, email blasts, and announcements on our website.

Comment: Commenter suggested that STrR's benchmark for PY 2021 is too low at 0.2 and should be higher, stating that the ratio of the number of observed transfusions being 1/5 of the number of those expected seems unrealistic and difficult to achieve, especially if it was the 90th percentile of national performance in 2016. The commenter also stated that few providers received a 10 on the STrR measure.

Response: We thank the commenter for this feedback, but we disagree and note that national data dictates the performance standards levels that we adopt under the ESRD QIP.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to substitute performance standards, achievement thresholds, and benchmarks if they are worse than they were in the prior payment year and to periodically re-baseline the BSI measure as needed, in PY 2021 and future payment years. In the performance standards we are

finalizing for the PY 2021 ESRD QIP in Table 15, we applied this substitution policy to four measures: the SRR measure, the SHR measure, the ICH CAHPS: Overall Rating of Nephrologists) measure, and the ICH CAHPS: Overall Rating of the Dialysis Facility measure.

We are also updating the performance standards, achievement thresholds, and benchmarks for the finalized PY 2021 ESRD QIP clinical measures as shown in Table 15, using the most recently available data.

TABLE 15: Finalized 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	51.79%	75.22%	62.80%
Catheter Rate	19.20%	5.47%	12.01%
Kt/V Composite	92.98%	99.14%	96.88%
Hypercalcemia	1.86%	0.00%	0.58%
Standardized Transfusion Ratio	1.684	0.200	0.847
Standardized Readmission Ratio	1.268	0.629	0.998
NHSN Bloodstream Infection	1.479	0	0.694
SHR measure	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	58.09%	78.52%	67.81%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16%	72.03%	62.34%
ICH CAHPS: Providing Information to Patients	73.90%	87.07%	80.38%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12%	77.46%	63.04%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98%	82.48%	67.93%

Data sources: VAT measures: 2016 CROWNWeb; STrR, SHR: 2016 Medicare claims; SRR: 2017 Medicare claims; Kt/V: 2017 CROWNWeb and Medicare claims; Hypercalcemia: 2017 CROWNWeb; NHSN: 2017 CDC, ICH CAHPS: CMS 2017.

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

As described in the CY 2019 ESRD PPS proposed rule (83 FR 34334 through 34335), we discussed our establishment of 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 to remove four reporting measures from the ESRD QIP measure set, beginning with PY 2021 (83 FR 34339 through 34340). As described above, we are finalizing that proposal. We also proposed to make changes to the measure domains and weights (83 FR 34341 through 34342).

a. Revision to Measure Domains Beginning with the PY 2021 ESRD QIP

To more closely align with the Meaningful Measures Initiative, in the CY 2019 ESRD PPS proposed rule (83 FR 34341 through 34342), we proposed 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). We stated that 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 also proposed to continue use of the Patient Safety Domain. We stated that 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 also proposed 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 the CY 2019 ESRD PPS proposed rule and our proposals in section IV.B.3.b of the CY 2019 ESRD PPS 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, were finalized.

Comment: Commenter supported our proposal to restructure the ESRD QIP's domains, suggesting that such efforts streamline the Program and ensures that patient and family engagement is a cornerstone of the QIP. Another commenter supported our proposal to remove the Reporting Domain, noting that the policy will enable CMS to focus on metrics that improve clinical outcomes and reduces complexity. Another commenter expressed support for reorganizing the Clinical Domain into three distinct domains.

Response: We thank the commenters for their support.

Comment: Commenter urged us to develop a pediatric CAHPS Survey to allow pediatric dialysis facilities to participate fully in the QIP, noting that our proposed domain changes will leave these facilities able to participate in only 3 of the new domains in the absence of a CAHPS Survey that captures their population.

Response: We thank the commenter for this feedback. The current ICH CAHPS measure excludes pediatric patients because the survey is not validated for pediatric patients. We intend to examine what modifications to the survey might be necessary to include these patients in the future.

Final Rule Action: After considering public comments, we are finalizing our proposal to update the measure domains, beginning with the PY 2021 ESRD QIP, without change. The finalized domains beginning in PY 2021 are the Patient & Family Engagement Domain, the Care Coordination Domain, the Clinical Care Domain, and the Safety Domain.

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

We proposed 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 16. We stated our belief 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 proposed to assign the Clinical Care Domain the highest weight because it contains the largest number of measures. We proposed 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 stated that we continue to believe that the measures in the Patient & Family Engagement and Safety domains address important clinical topics, but we also concluded that placing more weighting on measures more directly tied to clinical outcomes would be the most appropriate method to structure the ESRD QIP's measure domains.

We also proposed 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 16. We stated that our proposal was 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 16: 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% of TPS
CARE COORDINATION MEASURE DOMAIN	
SRR measure	14.00%
SHR measure	14.00%
Clinical Depression and Follow-Up reporting measure	2.00%
	30% of TPS
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	6.00%
Vascular Access Type measure topic*	6.00%
Hypercalcemia measure	3.00%
SrR measure	22.00%
Ultrafiltration Rate reporting measure	3.00%
	40% of TPS
SAFETY MEASURE DOMAIN	
NHSN BSI measure	9.00%
NHSN Dialysis Event reporting measure	6.00%
	15% of TPS
*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 16, we proposed 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 also proposed 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 proposed 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 did not propose any changes to the two measures included in the Safety Measure Domain: NHSN BSI and NSHN Dialysis Event measures. We stated that 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 invited public comment on our proposed domain and measure weighting proposals.

Comment: A commenter supported our proposal to reduce the weight assigned to the ICH CAHPS Survey from 18 percent to 15 percent given the challenges associated with the survey, including low response rates, and the large percentage of facilities that cannot be scored on the measure.

Response: We thank the commenter for its support.

Comment: A commenter expressed concern that the VAT measure topic has a proposed topic weight of only 6 percent of the TPS, stating that vascular access is highly leveraged with respect to patient morbidity and mortality. The commenter noted that since 2004, CMS has advocated for a “Fistula First Catheter Last” approach for vascular access use. The commenter also noted that catheter use rates have leveled off since 2013, and stated that this recent trend is an indication that progress on shifting the balance of vascular access use has halted. The commenter also stated that given the lack of progress in shifting the balance in recent years, it is

counterproductive to decrease the VAT topic's weight below the current level of 13.5 percent. In addition, the commenter suggested adding to the VAT measure topic some or all of the 14 percentage points currently proposed to be added to the STrR measure.

Response: We thank the commenter for this feedback and agree that the VAT measure topic's proposed weight of 6 percent is too low given the importance of vascular access for patient outcomes. After further consideration of the importance of the VAT measure topic to clinical outcomes for dialysis patients, we are finalizing that the VAT measure topic will receive 12 percent weight.

Comment: Several commenters were concerned about the weight assigned to the STrR measure. One commenter was concerned about our proposal to increase the STrR measure's weight given the validity issues associated with the ICD-10-CM/PCS transition. The commenter noted that the proposal would make the STrR measure the highest-weighted measure in the QIP even though the measure tracks a clinical condition that may not reflect anemia management at the dialysis facility. The commenter also noted that many hospitals may not code blood transfusions accurately given the increased specificity requirements of the ICD-10-CM/PCS system and encouraged us to assess the measure's validity before attributing significant weight to it. Another commenter recommended reducing the weight of the STrR measure, stating that transfusions are only a surrogate for very low hemoglobin, are not typically in the dialysis facility's control, and may not be accurately ascertained due to hospital reporting patterns. The commenter noted that many facilities do not have sufficient ICH CAHPS Surveys to be scored on the measure and for those facilities, the STrR measure will have a weight that is more than 25 percent of their TPS. Another commenter was concerned that facilities are not currently able to independently validate the third-party data used for STrR calculations and cannot correct hospital

or outpatient facility claims. Another commenter believed that anemia management is a critically important clinical outcome but suggested that heavy weighting proposed for the STrR measure is concerning given the coding and validity concerns associated with the measure. The commenter noted that blood transfusions often occur in the hospital setting, which is outside the dialysis facility's control. The commenter stated that we should not place that much weight on a single measure unless we identify a significant performance gap, the measure has met NQF's standards for reliability and validity, and clinicians and patients agree that the measure addresses a critical opportunity for quality improvement.

Another commenter did not agree with the proposed weight for the STrR measure, suggesting that patients often need transfusions for reasons unrelated to ESRD, and that dialysis facilities should not be penalized for transfusions unrelated to dialysis care. The commenter also noted that hospital-based dialysis facilities often accept all patients regardless of acuity or comorbidities, resulting in higher transfusion ratios than standalone facilities, and believed that weighting the STrR measure at 22 percent could affect access to care if facilities start limiting the number of high acuity patients they accept.

Response: We thank the commenters for this feedback. Given the concerns these commenters have raised about the STrR measure's validity and the significant percentage of facilities that are not eligible to receive an ICH CAHPS score, we will finalize a lower weight (10 percent) than proposed for the STrR measure and, after additional consideration of our clinical priorities as shaped by the Meaningful Measures Initiative, will adjust certain other measures' weights within the Clinical Care domain to account for that change. We are not adjusting weights in the other domains and will finalize the weights of the measures in those domains as proposed. However, as we discuss in more detail later in this final rule, we are also

finalizing a different weighting redistribution policy to account for commenters' concerns about how the measures would be re-weighted if a facility reports data for some, but not all, of the measures in a domain.

Specifically, after further consideration of the public comments, the validity concerns raised about the STrR measure, the importance of the VAT measure topic to dialysis patients, and our clinical priorities as shaped by the Meaningful Measures initiative, we are finalizing that the STrR measure will be weighted at 10 percent of the TPS, instead of 22 percent as proposed. We determined that a 10 percent weight for the measure more appropriately captures the measure's clinical significance, as shaped by the Meaningful Measures Initiative's priorities, and addresses concerns raised by commenters about the measure's validity and that the measure could be weighted too highly when facilities are missing scores from other measures. We are also finalizing that the VAT measure topic will be weighted at 12 percent of the TPS. To account for these changes and retain the same overall domain weight for the Clinical Care domain, we are finalizing that that the Kt/V measure will be weighted at 9 percent of the TPS and the Ultrafiltration measure will be weighted at 6 percent of the TPS. We believe that these changes respond to commenters' concerns about the proposed measure weights, and ensure that our clinical quality priorities continue to be reflected in the Program's scores.

Comment: Some commenters raised concerns about the reliability and validity of the StrR measure and the measure's sensitivity to changes in coding practices related to the ICD-10 conversion. The commenters also believed that the STrR measure should be replaced because facilities are being penalized for transfusions that occur outside of that facility's control.

Response: We thank the commenters for their feedback. As already noted, we are finalizing a lower weight for the STrR measure due to commenters' concerns about the overall

measure weighting proposal. However, we do not agree that the STrR measure is invalid, and we continue to believe that the STrR measure ensures that dialysis facilities do not underutilize ESAs and, as a result, play a role in more frequent red-blood-cell transfusions. Additionally, we continue to believe that the STrR measure, along with other measures in the ESRD QIP, ensure that dialysis facilities fulfill their shared responsibilities to work with other types of providers to provide the best possible care and ensure their patients' continued health.

Comment: A commenter requested that we provide additional justification for our proposals to update the PY 2021 measure weights, noting that two measures (dialysis adequacy and vascular access measures) are set to decrease in weight by more than half, and that we proposed to more than double the weight assigned to the STrR measure.

Response: We thank the commenter for this feedback. We proposed the PY 2021 domain weighting changes to reflect what we believed to be the clinical priorities assessed by the quality measures, informed by the Meaningful Measures Initiative. However, as noted in response to other comments, we are finalizing a lower weight for the STrR measure than proposed and will finalize a 9 percent weight for the Kt/V measure to account for the lower STrR weight.

Comment: A commenter was concerned about the proposed domain changes, stating that our proposal to provide a TPS to any facility with at least one measure in at least two domains would only result in a small number of additional facilities receiving a TPS.

Response: We thank the commenter for this feedback. However, while the commenter may be correct that the proposal may only result in a small number of additional facilities receiving a TPS, we believe that adjustment to our policies to be warranted to ensure that the ESRD QIP can provide incentives to improve care quality in as many dialysis facilities as

possible and to accommodate the changes that we proposed to the measure set. While the policy's effect may be small, we believe it to be an appropriate policy change to encourage participation in the Program.

Comment: A commenter expressed significant concern about the proposed new domain weights and the influence that the StrR and ICH CAHPS measures have on the total performance score, especially because the commenter believed the two measures have validity issues. Commenter suggested that CMS weight the catheter measure higher than the fistulas, contending that equal weighing of the two measures and the lack of a graft measure has resulted in patients experiencing clinically inappropriate AV fistula placement attempts. Commenter also stated that the evidence that AV fistulas and AV grafts are preferable for improved outcomes is significant, and that giving the catheter measure a greater weight supports a "catheter last" approach.

Another commenter raised concerns the VAT measure topic weight is too low. The commenter stated that vascular access is critically important to patients, is modifiable by dialysis facilities, and is a key factor influencing infection risk, hospitalizations, and death. The commenter also stated that the VAT topic's near topped out status can be addressed in other ways, including through modified achievement thresholds that permit greater individualization and incorporation of the newly revised VAT measures that account for some patient factors. Another commenter suggested that we increase the weight placed on the VAT measure topic to incentivize facilities to promote fistula use.

Response: We thank the commenters for their feedback. We may consider differential weighting for the VAT measure in the future, but we do not believe it would be appropriate to separate the measures for weighting purposes at this time. Catheter reduction and increased use of AV fistula are both important steps to improve patient care, and are tightly interrelated, so we

do not want to penalize providers or facilities twice for related outcomes. Further details about our view of the appropriateness of maintaining the VAT measures as a topic are available in the CY 2013 ESRD PPS final rule (76 FR 70264). As discussed in response to other commenters, we proposed these domain weight changes to reflect the clinical importance we ascribe to each quality measure, as informed by the Meaningful Measures Initiative's priorities, but after consideration of the comments, we are finalizing a lower weight for the STrR measure and a higher weight for the VAT measure topic.

We do not believe that the ICH CAHPS Survey has validity issues that would necessitate a change to its weighting. However, we will continue monitoring survey performance and will consider additional ways to improve its administration to minimize the burden undertaken by facilities and beneficiaries, and to otherwise improve its efficiency.

Comment: Commenter recommended that we maintain the StrR measure weight near the CY 2018 level of 8.25 percent, suggesting that the proposed increase in measure weight from 8.25 percent to 22 percent in PY 2021 is disproportionate compared to other measures of equal or greater clinical importance, especially given its concerns previously raised about the STrR measure.

Response: We thank the commenter for this suggestion. As discussed more fully above, we are finalizing a 10 percent weight for the STrR measure to reflect the concerns raised by commenters, and we believe this final policy is responsive to the commenter's concern about disproportionate weight being assigned to the STrR measure.

Comment: A commenter recommended reducing the weight of the STrR measure from 22 percent to 12 percent (equal to the SRR and SHR measures) and suggesting that CMS consider increasing the current weight of the ICH CAHPS and Depression reporting measures.

The commenter also recommended a series of changes to the proposed domain weights for PY 2021, including reducing the SRR and SHR measure weights slightly, increasing the Clinical Depression and Follow-up measure weights from 2 percent to 4 percent, increasing the Kt/V measure and VAT topic weights to 12 percent, reducing the STrR measure weight to 5 percent, maintaining the Anemia Management reporting measure in the QIP with a 4 percent weight, and increasing the Ultrafiltration Rate reporting measure to 4 percent.

Another commenter recommended increasing the weights of Kt/V and VAT measures to 11 and 15 percent respectively, stating that dialysis facilities are most likely to be able to influence these measures.

Response: We thank the commenters for their feedback. We are finalizing the STrR measure's weight at 10 percent and reweighting certain other measures within the Clinical Care domain to reflect the change to the STrR measure's weight because we believe that the Clinical Care domain should remain the most significant within the ESRD QIP, at a total domain weight of 40 percent. As previously noted, we believe that that this 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 believe that is appropriate to assign the Clinical Care Domain the highest weight because it contains the largest number of measures.

Comment: A commenter expressed concern that the dialysis facilities that are not eligible to be scored on certain measures will be subject to an even more distorted weighting approach if CMS finalizes its domain weighting proposals. The commenter stated that the StrR measure weight would increase from 22 percent to 26 percent of TPS for the 49 percent of

facilities ineligible for an ICH CAHPS score, based on CY 2016 industry data. The commenter also believed that the measure weighting imbalance would be even more extreme for facilities that predominantly or exclusively care for patients who dialyze at home, as they do not have enough data for the ICH CAHPS, NHSN BSI, NHSN dialysis event reporting, and ultrafiltration reporting measures and most are ineligible for the VAT measures. In addition, the commenter stated that for these facilities, 82 percent of the TPS would be based on 3 measures (SHR, SRR, and STTrR) and that this weighting approach may hinder greater adoption of home modalities. The commenter also suggested the development of an alternative measure weighing approach for home-only facilities.

Another commenter expressed concern that home-only dialysis programs will be scored on only two domains--Care Coordination and Clinical Care--using the proposed domain and weighting approach. The commenter stated that four measures currently do not apply to home-only programs due to either patient-level or facility-level exclusions: ultrafiltration, ICH CAHPS, HSNH BSI, and NHSN Dialysis Event. The commenter also stated that it is important to assess patient and family engagement among home dialysis patients, in part to address burn out issues. In addition, the commenter stated that infection complications are a well-recognized challenge for both home hemodialysis and peritoneal dialysis. The commenter was also concerned that the TPS of home-only programs will be heavily influenced by 3 claims-based measures: SHR, SRR, and STTrR, and that STTrR will comprise one-third of the TPS. The commenter also raised concerns that for small home-only programs, SHR and STTrR are not estimated. The commenter stated CMS to correct these distortions.

Another commenter stated that we should develop an alternative weighting scheme for facilities that predominantly or exclusively treat patients dialyzing at home. The commenter

stated that the current makeup of the QIP score could be a barrier to home dialysis uptake because low scores on a small number of measures can drastically affect facilities' TPSs. The commenter suggested that we consider applying the current low-volume scoring adjustment separately to home dialysis patients at each facility, which would alleviate the small sample size problem for those providers' scores.

Another commenter requested that CMS align the weights of applicable measures for all programs, including home-only programs, with a consistent definition of quality. The commenter stated that the QIP currently includes measures for programs that offer in-center hemodialysis, large home-only programs, and small home-only programs. The commenter also stated that this approach is not in the interest of CMS and Medicare ESRD beneficiaries who may use multiple dialysis modalities in multiple programs.

Response: We thank the commenters for their feedback. We acknowledge that the exclusions specified for the ICH CAHPS measure, the NHSN BSI measure, the NHSN dialysis event reporting measure, the Ultrafiltration reporting measure, and the measures comprising the VAT measure topic prevent most if not all facilities that predominantly or exclusively care for patients who dialyze at home from receiving a score on those measures. We are finalizing a lower weight for the STrR measure than proposed, and we believe the change will result in the STrR, SRR, and SHR comprising a smaller percentage of the TPS for these facilities.

Our intent is to include as many facilities in the Program as possible to provide broad-reaching incentives for facilities to improve the quality of care provided to their patients. We appreciate the commenter's concern regarding home dialysis facilities. However, we do not believe it is equitable to develop a separate policy for facilities that serve a large number of home dialysis facilities, as the Program currently accounts for these issues through policies that

reweight the TPS to account for missing measures. We will continue examining issues associated with home dialysis quality.

Comment: A commenter suggested that CMS conduct a more comprehensive review and update of the measure weights prior to the next annual update of the QIP, including giving stakeholders an opportunity to submit feedback and measure specific quantitative analysis of the measures' reliability and the opportunity for improvement provided for each measure. The commenter also recommended not finalizing the proposed weights and working with the kidney care community to refine the weighting policy.

Another commenter urged CMS to consider adopting additional criteria when determining measure and domain weights in the QIP, including the following: strength of evidence (including suggestive clinical or epidemiological studies or theoretical rationale); opportunity for improvement (including assessing the coefficient of variation for each measure); and clinical significance (which the commenter suggested could serve as a refinement to "clinical priorities" and could focus on the number of patients affected by measure compliance and the impact that compliance has on patient outcomes).

Response: While we understand the commenter's concern about opportunities for stakeholder input, the public comment period subsequent to the publication of the CY 2019 ESRD PPS proposed rule afforded stakeholders and the public an opportunity to provide feedback to CMS on the weights and this final rule provides an opportunity for CMS to respond to that feedback and revise the proposed weights if needed. As we have already noted, we are revising the weights of four measures in response to public comments on the CY 2019 ESRD PPS proposed rule. We intend to re-assess how the ESRD QIP domain weights being finalized in this final rule affect TPSs awarded under the Program in the future, and we always welcome

stakeholder feedback on our policies and suggestions for improvement.

We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden, and we therefore believe we considered the factors suggested by one of the commenters. We also consider criteria previously used to determine appropriate domain and measures weights (see the CY 2015 ESRD PPS final rule, (79 FR 66214)), including (1) The number of measures and measure topics in a proposed domain; (2) how much experience facilities have had with the measures and measure topics in a proposed domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (that is, the Meaningful Measures Initiative priorities, which includes our preferred emphasis on patient outcomes).¹³ However, we will consider the commenter's specific suggestions for suggestive clinical studies, assessing coefficients of variation, and the number of patients affected by measure compliance in future rulemaking.

Comment: Some commenters opposed the proposed weight of 9 percent for the NHSN BSI measure, suggesting that the BSI measure counts all infections regardless of whether the infection was acquired at the ESRD facility or elsewhere. One commenter did not believe that ESRD facilities should be held accountable for infections acquired in other care settings and believed that we should reduce the BSI measure's weight or revise it to include only vascular access-related bloodstream infections. Another commenter supported the Safety Domain's weight but recommended that we convert that domain to a reporting domain due to the lack of validity in the NHSN BSI measure. The commenter recommended that at a minimum, the

¹³ In the CY 2015 ESRD PPS final rule (79 FR 66214), we referred to "subdomains" in two of these criteria. Since we are finalizing a domain structure that no longer employs subdomains, we have reworded to use the term "domains" instead.

NHSN Dialysis Event reporting measure should be assigned a higher value than the NHSN BSI clinical measure. The commenter stated that it is more critical to provide incentives for facilities to accurately track and examine their infection data and that this assessment will promote high quality dialysis care.

Response: We disagree with commenters' concerns about the BSI measure. As we stated when we adopted the NHSN BSI measure in the CY 2014 ESRD final rule (78 FR 72204 through 72207), healthcare-acquired infections are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities. BSIs are a pressing concern in a population where individuals are frequently immunocompromised and depend on regular vascular access to facilitate dialysis therapy. We continue to believe that accurately reporting dialysis events to the NSHN by dialysis facilities supports national goals for the reduction of healthcare-acquired infections. In light of the importance of monitoring and preventing infections in the ESRD population, and because a clinical measure would have a greater impact on clinical practice by holding facilities accountable for their actual performance, we adopted the NSHN BSI measure as a clinical measure. We continue to believe that tracking these infection events and rewarding facilities for minimizing these events is of critical importance to protecting patient safety and improving the quality of care provide to patients with ESRD.

Comment: A commenter suggested reducing the proposed weight of the Hypercalcemia measure, explaining its view that many patients continue experiencing challenges outside of dialysis facilities' control, including a lack of access to medications and poor health outcomes related to surgery for hyperparathyroidism and hypercalcemia.

Response: We thank the commenter for this feedback. We are not finalizing a different

weight for the Hypercalcemia measure in response to comments received on the CY 2019 ESRD PPS proposed rule because we believe that a weight of 3 percent aligns with the Meaningful Measure Initiative—specifically its priority to promote effective prevention and treatment of chronic disease.

Comment: One commenter opposed decreasing the Patient and Family Engagement Domain weight to 15 percent of the TPS. The commenter disagreed with our stated reasoning that this policy emphasizes the two domains most focused on clinical outcomes, suggesting instead that the Patient & Family Engagement focuses on patient outcomes and should therefore not be assigned decreased weight. The commenter noted that the NQF views patient assessments of their experience as a patient-reported outcome and suggested that the ICH CAHPS measure therefore assesses patient outcomes. The commenter also stated that the ICH CAHPS measure is closely aligned with Meaningful Measure objectives because it is outcome-based, patient-centered, and meaningful to patients, in addition to providing a significant opportunity for improvement. The commenter recognized the importance of clinical outcome measures in the Care Coordination and Clinical Care Domains but expressed concern that the proposed change demonstrates that less focus should be placed on improving patient experience.

Response: While we appreciate the commenter's concerns and agree in general that patients' assessments of their experience are important for clinical quality measurement, we are also cognizant of the challenges that many facilities have submitting enough ICH-CAHPS data to be scored on that measure. We have balanced the domain weight that we proposed for the ICH CAHPS Survey in accordance with that consideration as well as the high clinical priority that we place on the patient experience. We will continue monitoring facilities' focus on improving the patient experience and will consider whether we should revisit the ICH CAHPS

Survey's weighting in the future.

Comment: A commenter recommended that CMS refrain from decreasing the Patient and Family Engagement Domain weight and instead assign equal weights to the four domains for PY 2012 and future years. The commenter noted that the impact of the six ICH CAHPS measures is relatively smaller in the ESRD QIP compared to other CMS VBP programs. The commenter used the Hospital VBP Program as an example of a program that attributes equal weight to its four domains, noting that this approach encourages hospitals to focus on improvement in each of the four domains.

Response: While the commenter is correct that the Patient & Family Engagement domain receives less weight than the Care Coordination or Clinical Care domains under our proposals, we note that the Patient & Family Engagement domain contains just one measure: the ICH CAHPS Survey. After the reduction to the STrR measure that we are finalizing, the ICH CAHPS Survey will be the most heavily weighted measure in the QIP. We believe such a domain weighting will ensure that facilities focus on improving the patient experience. With respect to the commenter's suggestion that we consider equal domain weighting, or 25 percent for each domain, we do not believe assigning such a significant weight to the Patient & Family Engagement domain with its single measure would be appropriate or reflect our clinical priorities for dialysis patients because it would entail reducing significantly the weights that we have assigned to other measures, such as those placed in the Clinical Care domain, and increasing the weights of the measures that we have placed in the Safety domain.

Final Rule Action: After considering the public comments received, we are finalizing our domain and measure weighting policy for PY 2021 as reflected in Table 17. We are finalizing as proposed; the weights of the measures in the Patient & Family Engagement Domain, the Care

Coordination Domain, and the Safety Domain. We are also finalizing as proposed the weight of the Hypercalcemia measure, which is assigned to the Clinical Care Domain. We are finalizing different weights for the other measures in the Clinical Domain than we proposed. Specifically, we are increasing the Kt/V measure weight from 6 to 9 percent of the TPS; increasing the VAT measure topic weight from 6 to 12 percent of the TPS; decreasing the STrR measure weight from 22 to 10 percent of the TPS; and increasing the Ultrafiltration measure weight from 3 to 6 percent of the TPS.

TABLE 17: Finalized Measure and Domain 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% of TPS
CARE COORDINATION MEASURE DOMAIN	
SRR measure	14.00%
SHR measure	14.00%
Clinical Depression and Follow-Up reporting measure	2.00%
	30% of TPS
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	9.00%
Vascular Access Type measure topic*	12.00%
Hypercalcemia measure	3.00%
STrR measure	10.00%
Ultrafiltration Rate reporting measure	6.00%
	40% of TPS
SAFETY MEASURE DOMAIN	
NHSN BSI measure	9.00%
NHSN Dialysis Event reporting measure	6.00%
	15% of TPS
*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).	

Update to Eligibility Requirement for Receiving a TPS for a PY and New Weighting

Redistribution Policy (Reassignment of 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. In the CY 2019 ESRD PPS proposed rule (83 FR 34342), we proposed 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 proposed 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. We stated that 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. We also stated that the proposed approach would enable 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 stated in the CY 2019 ESRD PPS proposed rule that we had 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).

We stated that 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 proposed the second policy alternative. We proposed 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 proposed to assign a higher weight to measures that focus on outcomes and a lower weight to measures that focus on clinical processes. We stated that 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.

Therefore, based on these considerations, we proposed 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 stated that we had 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 also stated that we believed that this proportional reweighting would ensure ESRD QIP TPSs are calculated in a fair and equitable manner.

We invited public comment on this proposal.

Comment: A commenter was concerned that under our weighting redistribution proposal, a facility could receive a TPS based solely on two measures (as long as they are assigned to different domains). The commenter believed that two measures is not sufficient to accurately assess the quality of care provided at a facility. The commenter was also concerned that the proposed policy could result in lower TPSs for home-only facilities because those facilities are the most likely to be eligible for scoring on a limited number of QIP measures.

Response: We thank the commenter for this feedback. However, we disagree with the commenter's view that facility performance on two measures is insufficient to accurately assess the quality of care provided at a facility. The Program's current policy, which allows facilities to receive a TPS if they receive a score on at least one reporting measure and at least one clinical measure, is a longstanding policy and one we believe that facilities understand well. As discussed in the CY 2012 ESRD PPS final rule (76 FR 70275), where we initially adopted that policy, we believe that maintaining a two-measure score minimum for receipt of a TPS continues to achieve this goal and provides as many dialysis facilities as possible with the opportunity to participate in the ESRD QIP.

We will continue monitoring the effects of the ESRD QIP's policies carefully and will continue assessing the effects that this eligibility policy will have on home-only dialysis facilities and other types of dialysis facilities that may receive scores on only a few measures. It is not our intention to affect access to home dialysis services negatively, and we do not believe that our policy does so. Rather, we intend to ensure that the Program provides incentives to improve care quality as broadly as possible among dialysis facilities and enables patients to pursue their preferred treatment modalities. However, we note that we intend for the ESRD QIP to provide incentives to improve quality no matter what treatment modality the patient prefers, which

includes home dialysis.

Comment: A commenter recommended modifying the proposed policy where a facility is eligible to be scored on at least one measure in any two out of four domains, so that the two measures cannot both be reporting measures. The commenter also suggested that CMS require one clinical measure and one reporting measure in any of the four domains.

Response: We thank the commenter for this feedback. Because we are finalizing the removal of four reporting measures, we do not believe it is likely that a facility would receive a TPS based entirely on two reporting measures, but in any case, we do not share the commenter's concern that a TPS based on two reporting measures would be invalid on its face. We have not seen any evidence that a TPS based on two reporting measures would be invalid. We have adopted this policy to ensure that the ESRD QIP can reach as many dialysis facilities as possible, and thus improve quality in as many facilities and possible. We do not believe that we should narrow the Program's reach in this form at this time, but we will consider whether we should adopt this type of requirement in the future.

Comment: A commenter was concerned about our proposal to redistribute domain weighting proportionately for facilities that do not receive a score on all ESRD QIP measures. The commenter stated that this approach could result in one or two quality measures, including the STrR, determining the majority of a facility's TPS. The commenter recommended that we redistribute the weights for missing measures equally across remaining measures, and more equally weight the measures generally.

Response: We appreciate the commenter's feedback and concerns that the STrR measure's weight will comprise a significant share of the TPS for some facilities. Given these concerns, as well as others raised by other commenters and summarized earlier in this section—

specifically, that the StrR measure weight would increase from 22 percent to 26 percent of TPS for the roughly 49 percent of facilities ineligible for an ICH CAHPS score, and that facilities that predominantly or exclusively care for patients that dialyze at home would be scored predominately on only a handful of measures—we are not finalizing our proposed weight redistribution policy. Instead, we are finalizing that if a facility does not receive a score on any of the measures in a domain, then that domain’s weight will be redistributed evenly across the remaining domains and then evenly across the measures within each of those domains on which the facility receives a score. Additionally, if a facility receives a score on some, but not all of the measures within a domain, the weight of the measure(s) for which a score is missing will be redistributed evenly across the other measures in that domain.

The weighting redistribution policy we are finalizing differs from the two policy alternatives discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34342). We are not finalizing our proposed weight redistribution policy because we agree with commenters’ concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures. We also reconsidered the other policy alternative discussed in the CY 2019 ESRD PPS proposed rule but still believe that this policy alternative would not maintain the Meaningful Measures Initiative priorities in measure weights as effectively as we prefer.

We then considered how best to address commenters’ concerns while maintaining the Meaningful Measures Initiative priorities and determined that the policy we are finalizing accomplishes this objective. Our finalized policy maintains the Meaningful Measures Initiative priorities and our preferred emphasis on those topic areas because when a facility is not scored on a measure, the domain weights will be the same as the domain weights of a complete measure set (unless an entire domain’s worth of measures is missing, in which case the domain’s weight

would be redistributed across the remaining domains; for example, if a facility did not receive an ICH CAHPS score, one-third of the Patient & Family Engagement Domain's weight of 15 percent would be distributed to each of the three remaining domains). Our finalized policy also addresses commenters concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures because the weight of measures for which a facility does not receive a score is redistributed evenly within its domain rather than proportionately across the entire measure set; measures with high weights will not receive the largest share of redistributed weights.

Final Rule Action: After considering the public comments we received, we are not finalizing our proposed weighting redistribution policy or the alternative discussed in the CY 2019 ESRD PPS proposed rule. Instead, we are finalizing that we will redistribute the weight of any measures within a domain for which a facility does not receive a score evenly across the other measures in that domain, and if a facility does not receive a score on any measures within a domain, we will redistribute that domain's entire weight evenly across the remaining domains, and then evenly across the measures within each of those domains on which the facility receives a score. We are also finalizing our proposal to consider facilities eligible to receive a TPS if they receive at least one measure score in two of the four domains.

4. 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 proposed to update this policy. We stated that under the proposed policy, facilities would be required 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. We stated that 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 also stated our belief that this policy would appropriately balance our desire to incentivize prompt participation in the ESRD QIP with the practical challenges facing new ESRD facilities as they begin operations.

We invited public comments on this proposal.

Comment: Some commenters expressed support for the grace period provided to new

facilities before they are required to begin reporting QIP data. One commenter appreciated that CMS is continuing to take provider feedback on this issue into consideration and stated that the extension for new facilities will allow them to complete the necessary steps to enroll in NHSN. Another commenter appreciated that the policy relies on the CCN effective date rather than the facility open date.

Response: We thank the commenters for their support.

Comment: A commenter strongly supported the proposal to update the requirement to begin reporting data for the QIP, noting that this policy update takes into consideration the time it takes new facilities to get up to speed on all required web-based data collection systems. The commenter supported using a full year's worth of data for both NHSN measures and strongly suggested requiring a full year's worth of data for all other standardized measures. The commenter requested clarification on how the updated policy affects measure eligibility and whether the updated policy should be changed to beginning 4 months after the month of certification.

Response: We thank the commenter for its support and will consider whether we should require a full year's worth of data for all measures in cases when a facility is new. We do not believe it is necessary to shift the reporting deadline from the first day of the month that is 4 months after the CCN eligibility date. We believe the policy as proposed is simpler for facilities to understand than adjusting reporting dates based on the specific day of the month that the facility received its CCN.

Table 18 summarizes the minimum data requirements for measure eligibility, including the updated requirement for new facilities.

TABLE 18: Eligibility Requirements Scoring on ESRD QIP Measures

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
NHSN Bloodstream Infection (Clinical)	11 qualifying patients	Before October 1 of the performance period that applies to the program year	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before October 1 of the performance period that applies to the program year	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1 of the performance period that applies to the program year	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 after the performance period that applies to the program year	N/A
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before April 1 after the performance period that	N/A

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
		applies to the program year	

Comment: A commenter suggested that we consider applying the proposed updated new facility policy to NHSN measures, noting that facilities with CCN eligibility dates late in the year may be penalized for complying with the new requirement but not submitting a full 12 months of data to NHSN.

Response: We thank the commenter for this suggestion. Under our current policy, facilities that do not submit a full 12 months of data to NHSN are not eligible to be scored on the NHSN measures under the ESRD QIP for that payment year and, as a result, are scored only on the measures for which they have submitted sufficient data.

Final Rule Action: After considering comments received, we are finalizing our proposed update to the requirement for new facilities to begin reporting ESRD QIP data, beginning with the PY 2021 ESRD QIP.

5. Estimated Payment Reductions 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).

In the CY 2019 ESRD PPS proposed rule (83 FR 34343), we stated that 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

also 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 that we described in the CY 2019 ESRD PPS proposed rule (83 FR 34340), we estimated in the CY 2019 ESRD PPS proposed rule that a facility must meet or exceed a minimum TPS of 56 for PY 2021. For all of the clinical measures, we stated that these estimates were based on CY 2017 data. We also proposed 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 19.

TABLE 19: Estimated Payment Reduction Scale for PY 2021 Based on the Most Recently Available Data

<u>Total performance score</u>	<u>Reduction (%)</u>
<u>100-57</u>	<u>0%</u>
<u>56-47</u>	<u>0.5%</u>
<u>46-37</u>	<u>1.0%</u>
<u>36-27</u>	<u>1.5%</u>
<u>26-0</u>	<u>2.0%</u>

We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34343) that we intended 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 received a number of comments on the estimated payment reductions.

Comment: Several commenters expressed concern about the effects of the proposed domain weighting changes on payment reductions under the QIP, noting that an analysis of PY 2018 data showed that the proposed weighting system would result in a slightly lower median

TPS and an increasing number of individual facilities with a decrease in their TPS. Another commenter requested that we provide a policy rationale for the projected increases in payment penalties. One commenter recommended that CMS work with the community to modify the TPS methodology, suggesting that the increase in projected payment penalties over the past few rule cycles does not reflect underlying measure performance trends. One commenter also expressed concern about the estimates showing that southern states will experience larger payment reductions than other parts of the country and suggested that we consider scoring facilities within peer groups rather than on a national basis.

Response: We understand the commenters' concern and we are willing to work with the community to understand specific concerns about the TPS calculation. However, we note that the TPS's specific composition changes year over year as we propose and adopt new measures and as we weight those measures in accordance with our priorities. Our adoption of several outcome and patient experience of care measures (such as the STeER measure and the ICH CAHPS survey) with large variation in aggregate performance and room for improvement in more recent years of the QIP has contributed to an increase in the number of facilities that are receiving payment reductions. We also proposed domain weights changes to reflect the ESRD QIP's changing measure set. These changes have included shifts in clinical priorities, removing measures where there is little room for improvement, and adding measures where facilities' performance is broader. We believe that some increases in payment penalties are inevitable as the Program's measure set changes, particularly as we accumulate sufficient data to assess facilities on measure performance and not simply on reporting. As a result of these policy changes, we believe it is reasonable for the payment reductions to shift even if performance on some measures is comparatively high. We will continue monitoring regional and other

differences in ESRD QIP performance scores by facility type or other factors.

Comment: A commenter requested that CMS extend the preview period for PY 2021 and PY 2022 to at least 60 days given the number of facilities estimated to receive a payment reduction in those years, stating that facilities need more time to analyze their TPSs.

Response: We do not believe we need to extend the preview period at this time because we have not observed any relationship between the number of facilities receiving a payment reduction and submitted inquiries. That is, we do not believe that a facility's receiving a payment reduction necessitates a preview period request, and to date, the 30-day period has been long enough to accommodate facilities' requests. We will monitor this issue and if necessary, will propose to address it in the future.

Final Rule Action: After consideration of the public comments received and an analysis of the most recently available data, we are finalizing that the minimum TPS for PY 2021 will be 56. We are also finalizing the payment reduction scale shown in Table 20.

TABLE 20: Finalized Payment Reduction Scale for PY 2021 Based on the Most Recently Available Data

<u>Total performance score</u>	<u>Reduction (%)</u>
<u>100-56</u>	<u>0%</u>
<u>55-46</u>	<u>0.5%</u>
<u>45-36</u>	<u>1.0%</u>
<u>35-26</u>	<u>1.5%</u>
<u>25-0</u>	<u>2.0%</u>

6. Data Validation Policies for PY 2021 and Subsequent Years

In the CY 2019 ESRD PPS proposed rule (83 FR 34343), we stated that 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 noted in the CY 2019 ESRD PPS proposed rule that we had 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 stated that we had 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.

We stated that based on this analysis, we believed that our validation methodology produces reliable results and can be used to ensure that accurate ESRD QIP data are reported to

CROWNWeb. Therefore, we proposed 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.

We also discussed the data that is submitted to the NSHN, and how 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 stated that 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 also stated that we had 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 proposed in the CY 2019 ESRD PPS proposed rule (83 FR 34343 through 34344) 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 proposed 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 proposed 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 also proposed to continue targeted validation.

We invited comments on these proposals. We also invited 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.

The comments and our responses to the comments on our data validation proposals are set forth below.

Comment: A commenter supported our proposal to increase the number of facilities selected for NHSN validation, noting that accurate reporting by all facilities will ensure that we are able to set accurate benchmarks and performance standards.

Response: We thank the commenter for its support.

Comment: A commenter supported the expansion of the NHSN validation study and the

adaptation of the CROWNWeb validation study into a permanent feature of the Program.

Response: We thank the commenter for its support.

Comment: A commenter supported our proposal to expand the NHSN validation study in PY 2021 and PY 2022 but suggested that we should consider expanding the validation sample to 10 percent of all facilities.

Response: We thank the commenter for its support. However, we do not believe that a 10 percent sample is appropriate at this time principally because such an increase in sample size would represent a significant increase in the reporting burden for facilities selected for validation. We considered several factors when developing our sample size proposal, including the overall burden to facilities, number of facilities validated, and reliability of validation results at the facility level.

Our goal for the NHSN validation study is to ensure that the data reported for purposes of the QIP is accurate. We are committed to validating data, monitoring the quality of submitted data, and identifying opportunities to improve the accuracy of data reported.

Comment: A commenter supported reselecting for the following year facilities that have undergone NHSN validation and have not met the established reporting or data accuracy threshold. The commenter believed that lessons learned from validation are important to share with all ESRD facilities as a way to ensure overall NHSN data quality.

Response: We thank the commenter for its feedback.

Comment: Several commenters expressed support for increasing the number of facilities included in the NHSN validation study to 300. One commenter also raised concerns that this facility increase will not resolve substantial underlying problems with the NHSN BSI measure.

Response: We thank the commenters for their support. We believe that validating

NHSN data will ensure that NHSN measures' data are accurate and complete and will therefore enable us to address any further methodological issues with NHSN measures as needed.

Comment: A commenter strongly opposed expanding the validation program as proposed. The commenter stated that a validation program expansion suggests that previous validation cycles have identified problems or inconclusive results on measure validity. The commenter suggested that prior results should be released and once the data collection tools are validated, the validation program should continue under a process that ensures facilities due process rights under the U.S. Constitution. The commenter believed that the current timeframes and penalties do not give facilities due process and that CMS is auditing facilities, not validating their data. The commenter also stated that this audit should include the right to appeal adverse decisions.

Response: We thank the commenter for this feedback. The purpose of our validation program is to assess the accuracy and completeness of data reported to NHSN and scored under the ESRD QIP, and we have expanded it to ensure that we have the sufficient statistical power to do so.

We intend to publish the results of our CY 2018 validation studies at the end of 2019, but we do not agree with the commenter's characterization of our validation studies as audits. As we noted in the CY 2017 ESRD PPS final rule (81 FR 77895), the ultimate objective of our validation studies is to improve the validity of QIP data reported to CROWNWeb and to NHSN, not to penalize facilities for reporting invalid data. We note further that we have never penalized facilities for reporting invalid data in either of the validation studies, and if we were to consider proposing to do this in the future, we would also consider implementing an appeal process. We also note that the ESRD QIP Inquiry Period currently gives facilities an opportunity to inquire

and receive feedback on their performance score and associated payment, and we will consider whether to incorporate feedback mechanisms into our validation processes in the future.

Comment: Some commenters opposed the NHSN validation study's expansion to 40 records per facility and recommended that it be reduced to 20 records per facility. One commenter supported targeting NHSN studies for dialysis facilities that might be under-reporting, requested information about the NHSN study results, and suggested that poor results should trigger an update to the benchmarks and achievement thresholds for the BSI measure. The commenter also noted that CMS requested ideas related to penalizing facilities that do not meet established reporting or data accuracy thresholds but noted that both validation studies already include a penalty associated with measure performance. The commenter supported targeted education, raised concerns that the annual training is not checked to ensure it is completed, and suggested having targeted training within the NHSN system itself. The comment also supported introducing a bonus such as adding points to the TPS, to encourage accurate reporting.

Another commenter believed that it is inappropriate to try to validate an invalid measure by imposing a burdensome data validation program on any provider. The commenter recommended that CMS suspend the use of the NHSN BSI measure and the reporting measure until they are validated outside of the QIP. Another commenter expressed concern that CMS has not validated CROWNWeb data or data for the NHSN Bloodstream Infection clinical measure and has not released the report summarizing the results of efforts to validate those data collection tools to date. The commenter requested that CMS first establish reliability and validity for the BSI measure before using it in the QIP and the TPS since CMS has noted in previous rulemaking that up to 60-80 percent of dialysis events are underreported and this high rate of underreporting

would not be present in a valid and reliable measure.

Response: We thank the commenters for their support for targeted NHSN validation and will consider whether we should introduce a scoring adjustment for accurate NHSN reporting.

We disagree that NHSN measures are unreliable, and we firmly believe that a robust validation effort will ensure that facilities are reporting accurate and comprehensive data to NHSN. We also disagree with comments stating that the measure is clinically invalid. The BSI measure is endorsed by the NQF, which closely reviews measures for clinical validity and evidence base. We therefore do not agree that we should suspend the BSI measure at this time.

Further, our NHSN dialysis event validation study has focused primarily on the feasibility of undertaking more comprehensive data validation activity. Prior pilot studies were initially conducted on nine dialysis facilities and subsequently on 35 randomly selected facilities. Validation studies on small sample sizes focused on improving our understanding of the time and resources required to accomplish validation activity on a larger scale. A small sample size below thresholds lacks precision and is subject to large sampling variability. Hence, as a next step after the feasibility studies phase, we believe expanding the sample size of facilities to be validated is warranted to accurately and precisely estimate the extent of errors in dialysis event case classification (both under- and over-reporting).

In addition, as already noted, we intend to publish the results of our CY 2018 validation studies in 2019.

Comment: A commenter was concerned about the burden associated with validation activities and encouraged us to consider alternative approaches to data validation, potentially including requesting records related only to the specific clinical topic being validated, allowing a longer timeline such as 90 days for facilities to respond to requests, and electronic information

exchange.

Response: While the focus of NHSN Dialysis Event validation lies on positive BSI, other candidate events (pus, increased redness or swelling, and IV antibiotic start) tend to co-occur frequently. Since most of these events are uncommon, to assure that at least 10 candidate events are reviewed per facility for the validation timeframe, additional patient lists for example, individuals with pus, increased redness or swelling, and individuals with IV antibiotic start (in addition to positive BSI) are also requested.

We believe that allowing 90 days for facilities to respond to requests is not feasible because our goal is to provide facilities with timely feedback about reporting accuracy. Validation studies are conducted within a timeframe of 24- through 30 weeks and addition of more facility response time is prohibitive due to the time constraints.

There is a potential that future exchange of medical records could be accomplished via electronic information exchange. As validation studies progress we aim to make the process less burdensome for facilities.

Comment: A commenter strongly agreed with our policy goal of reducing rates of bloodstream infections, but worried that NHSN-based reporting of these infections does not differentiate between those related to dialysis and those that are unrelated. The commenter also urged us to consider working with CDC to allow facilities to validate third-party data submitted to NHSN on BSIs.

Response: We thank the commenter for their feedback and we will consider it in future payment years. However, we would like to clarify that data validation is an ESRD QIP policy intended to ensure the accuracy of NHSN data scored under the QIP. We will continue to work with CDC on appropriate NHSN data accuracy policies.

Final Rule Action: After considering public comments received, we are finalizing our proposals to update the NHSN validation study and to adopt CROWNWeb validation as a permanent feature of the ESRD QIP, as proposed without change.

C. Requirements for the PY 2022 ESRD QIP

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

Since we are finalizing our proposal to remove four measures beginning with the PY 2021 ESRD QIP, the PY 2021 ESRD QIP measure set will 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 proposed 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. Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure

We proposed 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.¹⁴ Despite the benefits of kidney transplantation, the total number of transplants performed in the U.S. has stagnated since 2006.¹⁵ There is also wide variability in transplant rates across ESRD networks.¹⁶ Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, we stated in the CY 2019 ESRD PPS proposed rule that a quality 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

¹⁴ 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.

¹⁵ 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.

¹⁶ 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.

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 would 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 would provide 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 would be created each time he or she changes facility or treatment modality. Each record would represent a time period associated with a specific modality and dialysis facility. Each patient-month would be assigned to only one facility. A patient could be counted up to 12 times in a 12-month reporting period, and home dialysis would be 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 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 submitted the measure to the NQF for consideration of endorsement, and the Renal Standing Committee did not recommend the PPPW measure. Nonetheless, 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 conditional 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 proposed to adopt the PPPW measure beginning with the PY 2022 ESRD QIP. We noted also that there are currently no NQF-endorsed transplant measures that we could have considered, and that we believed we could adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We invited comments on this proposal.

The comments and our responses to the comments on our proposals are set forth below. We also address comments on the proposed Standardized Waitlist Ratio (SWR) measure (discussed further in a subsequent section of this final rule) in this section because commenters frequently addressed the PPPW and SWR measures together.

Comment: One commenter strongly supported the proposed PPPW measure.

Response: We thank the commenter for this support.

Comment: A commenter strongly supported CMS' proposals to adopt the PPPW and SWR measures, stating that timely access to transplantation for ESRD patients is widely acknowledged as important, and that longer wait times for transplants are associated with poorer outcomes. The commenter also noted the key role that dialysis facilities play in placing patients on transplant wait lists. The commenter offered to work with CMS on additional risk adjustment policies as needed but stated that CMS should not wait to adopt the measures. Another commenter stated that the proposed measures will ensure that dialysis facilities are held accountable for access to transplantation.

Response: We thank the commenters for their support.

Comment: Commenter supported our proposed adoption of the PPPW measure for the ESRD QIP but suggested that we accelerate its adoption to PY 2019 rather than waiting until PY 2022.

Response: We thank the commenter for this support, but we do not believe it is possible to accelerate the measure's adoption to PY 2019 since that would have meant adopting the measure for the CY 2017 performance period. Furthermore, we are unable to accelerate the adoption of the PPPW measure earlier than PY 2022 due to operational constraints.

Comment: A commenter raised concerns that the risk models for the PPPW and SWR measures will not adequately discriminate performance, noting that risk model testing showed an overall C-statistic of 0.72 for the PPW measure and 0.67 for the SWR measure. The commenter stated that a minimum C-statistic of 0.8 is a more appropriate indicator of a model's goodness of fit, predictive ability, and validity to represent meaningful differences among facilities.

Response: We believe that the reliability of the PPPW and SWR measures is appropriate based on recent literature and note that their reliability estimates are similar to other current NQF endorsed quality measures implemented by CMS.

Commenter: Some commenters expressed concerns about the PPPW and SWR measures' use, noting that dialysis facilities do not have control over transplant waitlists and that dialysis facilities should not have incentives to refer all patients for transplants. One commenter stated that dialysis facilities are unable to meaningfully impact their performance on these measures. Another commenter stated that numerous factors outside the facility's control determine whether an individual is placed on a transplant waitlist or receives an organ transplant. Other commenters stated that the transplant center decides whether a patient is added to a waitlist, not the dialysis facility. One commenter stated that the evaluation process includes

many obstacles and delays across multiple parties that are irrelevant to the dialysis facility and that this misattribution is misaligned with NQF's first "Attribution Model Guiding Principle", which says measure attribution models should fairly and accurately assign accountability. One commenter stated that other transplantation access measures more appropriately capture dialysis facilities' sphere of control over transplant waitlists. One commenter stated that hospitals set criteria for transplant waitlists and suggested that we work with transplant programs to find ways to align and streamline their criteria. The commenter also noted that transplant centers will not include patients on their waitlists unless they can prove they can pay for immunosuppressive drugs post-transplant.

One commenter suggested that patient-centered education about transplantation may be more useful for dialysis patients. Another commenter agreed that dialysis facilities have a role in educating patients about transplants, assisting patients with being evaluated, and keeping patients healthy enough to remain active on the waitlist but recommended that we work with the community to develop a more actionable transplant measure for dialysis facilities. The commenter suggested that we consider applying the PPPW measure to nephrologists participating in the Merit-Based Incentive Payment System.

Another commenter reiterated its belief that dialysis clinics should not be held accountable for transplants and urged us to report the transplant measures on the Dialysis Facility Compare site and not include them in the QIP. Another commenter suggested adoption of a transplant measures over which facilities have more control. Another commenter recommended that we develop alternative quality measures that more accurately reflect the care provided in dialysis facilities, such as measures of transplant education and/or referral for transplant evaluation.

Response: Waitlisting for transplantation is the culmination of a variety of preceding activities. These include (but are not limited to) education of patients about the transplant option, referral of patients to a transplant center for evaluation, completion of the evaluation process and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis facilities. Although some aspects of the waitlisting process may not entirely depend on facilities, such as the actual waitlisting decision by transplant centers, or a patient's choice about the transplantation option, these can also be nevertheless influenced by the dialysis facility. For example, through strong communication with transplant centers and advocacy for patients by dialysis facilities, as well as proper education, we believe dialysis facilities are well-positioned to provide encouragement and support of patients during their decision-making about the transplantation option. The waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis facilities. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis facilities can be and are already making towards access to transplantation, to the benefit of the patients under their care.

Comment: A commenter raised concerns about the PPPW and SWR measures. Commenter stated that many factors outside of dialysis facilities' control influence whether or not a patient is waitlisted, including changes in the patients' health status, overall transplant center performance, and the level of risk tolerance of a given transplant center. The commenter recommended adopting a reporting requirement for referrals to transplant centers instead, suggesting that it would increase CMS's understanding of referral patterns and assist with the development of appropriate policies and incentives to promote transplant in the future. The commenter also noted that the NQF declined to endorse the PPPW measure. The commenter

suggested that CMS explore the development of a process measure related to patient education about modality options and its documentation in patients' care plans. The commenter also recommended that CMS collaborate with the community to develop measures that synergize across the dialysis and transplant settings.

Response: We will consider the commenters' suggestions for additional measures on the transplant topic in the future. However, as we stated in the CY 2019 ESRD PPS proposed rule (83 FR 34344), we believe that the benefits of kidney transplantation as a renal replacement therapy modality are well-established, and we continue to believe that dialysis facilities should make every effort to ensure that their patients are appropriately wait-listed for transplants.

Comment: Some commenters opposed the adoption of the PPPW and SWR measures. One commenter believed that the two measures will not encourage transplants due to poor design. The commenter recommended that CMS develop a transplant measure that is actionable by dialysis facilities. Another commenter recommended that CMS work with transplant programs to align and streamline waitlist criteria and consider ways to create a single point of access for patients and transplant physicians to access potential living donors.

Another commenter stated that any transplant measures should be actionable by dialysis facilities and should meet other scientifically-based criteria. The commenter stated that the proposed PPPW and SWR measures do not assess what they purport to measure, and therefore will not incentivize transplants.

Some commenters stated that the NQF has not endorsed either the PPPW or the SWR. One commenter stated that the NQF's Renal Standing Committee reviewed the measures in the spring of 2018 and did not recommend either measure for endorsement, finding that the submitted evidence was focused on the impact of transplantation on patient outcomes rather than

the impact of transplant waitlisting, that the transplant facilities have varying selection criteria for their waitlists, and that the measure did not address patient preference to not receive a transplant. The commenter recommended the development of alternative measures that relate to the outcome of transplant rather than waitlisting.

Another commenter stated that ESRD facilities are not the barrier to placing patients on transplant lists. The commenter stated that the stagnant percentage of patients on waitlists since 2006 that we noted in the CY 2019 ESRD PPS proposed rule is due to the implementation of new conditions of participation for organ transplant centers in 2007, which may result in centers losing their CMS certification if enough organ grafts fail. The commenter further stated that transplant centers have thus become risk-averse and suggested that we review those conditions of participation again rather than adopt these measures. The commenter also stated that we should not incentivize ESRD facilities to increase the percentage of their patients on transplant waitlists if those patients are not appropriate for transplant services.

Response: We will consider working with transplant programs and stakeholders, including HRSA's Organ Procurement Organizations to align and streamline waitlist criteria within our current legal authorities. However, we disagree that the proposed measures will not encourage transplants. We believe that adopting these measures will encourage dialysis facilities to make every effort possible to place their patients on transplant waitlists and thereby ensure that their patients receive the benefits of that treatment modality.

We disagree with the concerns raised by the commenters about the PPPW and SWR measures not meeting scientifically-based criteria. We would like to clarify that the NQF submission included multiple high quality scientific studies demonstrating the positive impact of successful kidney transplantation on patient outcomes. Since deceased donation kidney

transplant does not legally occur in the U.S. without waitlisting, we continue to believe that the literature focus of the measure's submission was appropriate. We respectfully disagree with the Renal Standing Committee's view that the evidence we provided on the benefits of kidney transplantation was insufficient.

Although it is true that transplant facilities contribute to the variation in waitlisting, it is also true that extensive variation in dialysis facility referrals results in facility-level variation in waitlisting that is not well explained by available risk adjusters. This dialysis facility-level variation strongly suggests an opportunity for improvement in patient access to kidney transplantation through incentivization of dialysis facility involvement in preparing patients for transplantation.

Patient preference for or against kidney transplantation may well depend, at least in part, on information about the relative benefits of chronic dialysis vs. transplant provided by the dialysis facility. As noted above, dialysis facility-level variation in referrals for evaluation and follow-up strongly suggests opportunities for improvement in educating and preparing patients for transplantation.

We believe that the transplant topic is an important issue that should be covered in the QIP; the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy among ESRD patients are well-established.

We will consider reviewing the conditions of participation for organ transplant centers to evaluate whether prior policy changes have resulted in more risk-averse behavior by those centers. However, we do not agree that we should fail to adopt these measures as a result and note that measuring the percentage of patients waitlisted is a different clinical measurement than assessing patients that receive organ grafts. We believe a measure of patients waitlisted is more

appropriate than a measure of patients receiving organ grafts due principally to the scarcity of kidneys for transplant and long waiting times. Further, we believe a measure of patients waitlisted ensures that facilities work with transplant centers to prepare as many patients as possible and clinically appropriate for those procedures.

We also believe that both the PPPW measure and the SWR measure are clinically appropriate measures covering the transplant topic. However, in response to public comments received and in accordance with our Meaningful Measures-based priority of adopting a smaller, more parsimonious measure set, we are finalizing our proposal to adopt the PPPW measure beginning in PY 2022, and as discussed further in section IV.D.1 of this final rule, we are not finalizing our proposal to adopt the SWR measure beginning in PY 2024. We believe that the PPPW measure is more appropriate to include in the QIP at this time because the PPPW measure affects more patients and includes the SWR measure's population; the SWR measure has a 3-year period of performance versus the PPPW measure's 1-year period of performance, and the PPPW measure's reliability is higher than the SWR measure's reliability (0.72 versus 0.67). We have therefore concluded that the PPPW measure is more consistent with our policy goals of promoting kidney transplantation, and in the interest of adopting a more effective measure set, will finalize it and will not finalize the SWR measure. Adoption of one transplant measure rather than both will also reduce facility burden under the QIP because facilities will only need to track their progress on one transplant measure.

Comment: A commenter supported exploring transplantation measures for dialysis care quality but did not support the proposal to adopt the PPPW or SWR measures due to geographic variability in access to transplantation. The commenter stated that access to transplantation depends heavily on the dialysis facility's proximity to transplant programs. The commenter

suggested that CMS instead evaluate each facility based on the historical percentage of patients waitlisted at each facility.

Response: We will consider whether evaluating a historical percentage of patients waitlisted at each facility represents a viable quality measurement option. We will also examine issues related to geographic variability in access to transplantation. However, we do not believe that these concerns necessitate not finalizing measures of transplantation given the clinical benefits associated with that treatment modality.

Comment: A commenter supported our proposal to adopt the PPPW measure, stating that kidney transplantation is widely regarded as a better ESRD treatment option than dialysis for patients' clinical and quality of life outcomes.

Response: We thank the commenter for this support.

Comment: A commenter supported our desire to include transplant measures in the QIP and stated that pediatric dialysis facilities will be able to report the PPPW measure successfully.

Response: We thank the commenter for this support.

Comment: A commenter expressed concerns that the proposed PPPW measure would not address underlying care disparities for pediatric patients and suggested that CMS consider additional exclusion criteria such as excluding patients under 2 years of age and exclusions for patients with medical and sociodemographic criteria that may preclude transplantation.

Another commenter recommended that CMS consider risk-adjusting the PPPW and SWR measures using factors that take into consideration regional differences, eligibility criteria at the transplant center, and demographic variables such as family support, and insurance issues that may influence the likelihood of transplant waitlisting. Another commenter expressed concerns about dialysis patients' being unable to receive premium support payments for commercial health

insurance after transplantation, which may delay transplants as those patients cannot then demonstrate that they have a coverage source following the transplant.

Some commenters expressed concern that the PPPW and SWR measures include age as the only sociodemographic risk variable. They stated that transplant centers assess demographic factors such as family support, ability to adhere to medication regimens, capacity for follow-up, and insurance issues. One commenter stated that not accounting for other important biological and demographic variables raises concerns about validity for both measures but did not support adjusting for waitlisting based on economic factors or by race or ethnicity. Another commenter suggested examining geography as a risk variable, stating that regional variation in transplantation access is considerable and that these differences will change the share of patients waitlisted and affect performance measure scores. One commenter also raised concerns that the "not eligible" criteria for transplantation can differ by transplantation center location.

Response: We agree that financial and other social issues can pose substantial barriers to waitlisting for patients. However, they do not take away from the fact that many patients with these issues will still stand to benefit substantially from transplantation as compared with remaining on dialysis. As such, it is expected that dialysis facilities will work with transplant centers, advocate for patients and assist them in overcoming barriers to waitlisting to the extent possible. We also recognize that even with the best efforts, not all dialysis patients will ultimately be suitable candidates for waitlisting. Thresholds for the measures are assessed at the facility level. Examination of facility level measures essentially allows comparison of an individual facility's performance to a consensus standard, empirically set by the achievement of dialysis facilities across the nation. Through comparison with the performance of other facilities, these measures may help individual dialysis facilities identify opportunities for improvement in

their waitlisting rates.

Regarding geography, we examined this issue extensively and ultimately decided against including an adjustment for the following reasons:

1. The transplant center's geographic rate adjustment is not statistically significant in the model and is unstable dependent on how a small percent of missing values are handled.

2. The C-Index (a measure of goodness of fit) for both the model with and without this geographic adjustment is 0.72, suggesting no improvement in discrimination with inclusion of the geographic effect.

We will continue to examine issues associated with the pediatric population, including possible additional exclusions from transplant measures.

Comment: A commenter expressed support for the exclusion of patients admitted to hospice during the month of evaluation based on its belief that the transplantation access measures should not apply to persons with a limited life expectancy.

Response: We thank the commenter for this support.

Comment: A commenter recommended indicating that the PPPW measure is an intermediate outcome measure rather than a process measure.

Response: We have consulted with the NQF on this topic, and it currently classifies this measure as a process measure. We agree with that assessment since the measure assesses a clinical process – placement on a waitlist – rather than an outcome, such as successful kidney transplants.

Comment: A commenter agreed with CMS that dialysis facilities and transplant centers need to coordinate care related to the transplant referral and waitlisting process, including starting the transplant evaluation and starting the multiple tests and consultations needed for that

evaluation. However, the commenter raised concerns about adopting the PPPW measure as a clinical measure rather than a reporting measure. The commenter stated that when the technical expert panel (TEP) convened by CMS's contractor recommended that we adopt the PPPW as a clinical measure, the new kidney allocation system (KAS) on waitlisting was unknown. The commenter noted that the TEP also acknowledged recent evidence suggesting that the mere possibility that a PPPW measure was being developed for potential inclusion in the QIP has changed clinician behavior and reduced waitlisting rates. The commenter also stated that this change in clinician behavior may also be due to the new KAS, where wait-time begins at dialysis initiation, and has caused providers to wait until a patient has spent several years on dialysis prior to referral rather than refer patients early. In addition, the commenter raised concerns that a transplant evaluation conducted by a transplant center can take many months and that the distribution of transplant centers has geographic inequity. Another commenter also raised concerns that eligible patients may not be waitlisted due to factors outside of the dialysis facility's control, such as transplant center eligibility and the lack of NQF endorsement. The commenter recommended that CMS refer this issue to the ESRD Networks for further discussion with facilities.

Response: We understand the commenter's concerns. However, we do not believe that these concerns should prevent us from finalizing the PPPW measure because the measure incentivizes facilities to do what they can to ensure that their patients are waitlisted as timely as possible. We will continue discussions with the stakeholder community about barriers to organ transplants, but we view transplants as a clinically appropriate goal for dialysis patients. We note further that the measure's testing involved analyses that controlled for geography, and we did not observe any effects on the measure's reliability associated with geographic inequity.

Comment: A commenter stated that one PPPW exclusion has been changed since the measure was originally developed and that the measure being proposed for the QIP now contains an exclusion for "patients admitted to a skilled nursing facility at incidence or previously according to Form CMS 2728." The commenter expressed support for this change and recommended providing information on the impact of this exclusion on performance.

Response: We thank the commenter for its support. Our goal is to test all of our measures as a part of our measure maintenance and development process.

Comment: A commenter suggested that CMS provide for the PPPW and SWR measures a detailed description of measure scores, such as distribution by quartile, mean, median, standard deviation, and outliers, stating that this information is needed for stakeholders to assess the measures and review the measures' performance. The commenter also stated that with large sample sizes, statistically significant differences in performance may not be clinically meaningful.

Response: We thank the commenter for this feedback. We believe that this is a reasonable request and we will consider how to include this information in future versions of the measure methodology reports for each measure.

Comment: A commenter suggested that CMS develop a multi-pronged strategy to increase the kidney transplantation rate. The commenter suggested improving the consistency of information requirements for initial referrals across transplant centers and encouraging the exchange of information through electronic medical records. The commenter also suggested improving the organ donor supply, noting that increasing the number of patients on the waitlist without addressing the limited availability of health donor kidneys will have little effect on increasing the rate of successful transplantations.

Response: We thank the commenter for its suggestions. We will take them under consideration to the extent feasible within our legal authorities.

Comment: A commenter suggested that CMS consider adopting a measure on education for transplantation as a modality.

Response: We thank the commenter for its suggestion. We'll take it under consideration as part of our measure development work.

Comment: A commenter suggested that we consider adopting a measure comparing facilities' transplantation rates to their prior performance. The commenter suggested that this proposal, along with the PPPW measure, could ensure that dialysis facilities in all areas of the country (including those with differing waitlisting rates) work to improve their transplantation practices.

Response: We thank the commenter for its suggestion of a measure concept focused on improvement in transplantation rates. We will take it under consideration as part of our measure development efforts. We note, however, that we will assess performance on the PPPW on both achievement and improvement using the ESRD QIP's current measure scoring methodology. Based on our past experience using this methodology, we believe that dialysis facilities will be able to score points for improving their performance on the measure over time.

Comment: A commenter suggested that referral rates are more appropriate than waitlisting rates as a QIP measure but recognized that data challenges exist.

Response: We thank the commenter for its suggestion of a measure concept focused on transplantation referral rates. We will take it under consideration as part of our measure development work.

Final Rule Action: After considering public comments, we are finalizing our proposal to

add the PPPW measure to the ESRD QIP measure set beginning with PY 2022.

b. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)

Reporting Measure

We proposed 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.¹⁷ 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.¹⁸ 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

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

¹⁸ 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.

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_NQFendoredSpecs10-26-17.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.

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 report¹⁹. 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

¹⁹ Available at:
https://www.qualityforum.org/Publications/2018/02/2018_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.

can be significantly harmed by medication administration errors. We continue to believe that care coordination is a critical quality improvement topic. Therefore, we proposed 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.

The comments and our responses to the comments on our proposal are set forth below.

Comment: Several commenters supported our proposal to adopt the MedRec measure, stating that the measure has clinical merit. One commenter stated that the measure is NQF endorsed and that patients on dialysis are on numerous medications, have multiple prescribers and have frequent changes. Another commenter noted that medication management is extremely important for ESRD patients that often receive multiple prescriptions from numerous health care providers. Another commenter stated that the measure will improve patient care and safety.

Response: We thank the commenters for their support.

Comment: A commenter supported the MedRec measure but suggested that the QIP should include a limited set of measures that can more broadly assess facility performance on clinical topics.

Response: We thank the commenter for its support. We agree that the QIP should include a focused quality measure set, which is why we proposed to remove several reporting measures beginning with the PY 2021 ESRD QIP. We intend to continue examining the ESRD QIP measure set to ensure that it remains as effective as possible at providing incentives for high-quality care while minimizing the reporting burden on participating facilities. Further, we believe that the MedRec measure broadly assesses facility performance by focusing on a topic

critical to patient safety. By protecting patients from medication errors, dialysis facilities will ensure that their performance on quality measures accords with good clinical practices.

Comment: Two commenters supported the MedRec measure's adoption but suggested that we place it into the Care Coordination domain rather than the Safety domain in order to align with the Meaningful Measures Initiative priorities.

Response: We thank the commenter for their support. However, while we agree that medication reconciliation can be considered a measure of care coordination, we believe that it is more properly aligned with patient safety because patients can be harmed by medication errors.

Comment: A commenter supported our proposal to add the MedRec measure to the QIP beginning in PY 2022, noting that it is critically important for dialysis facilities to have the most accurate record possible of their patients' prescriptions, medications, and supplements.

Response: We thank the commenter for its support.

Comment: A commenter supported adoption of the MedRec measure. The commenter noted that requiring hospitals to provide data regarding patients' inpatient care to dialysis facilities would greatly facilitate dialysis facilities' ability to conduct medication reconciliation. The commenter also noted that the lack of interoperable EHRs hampers this type of data-sharing but recommended that CMS consider how it can better encourage hospitals to provide this information in a timely fashion.

Response: We thank the commenter for its support. We will take their feedback on the lack of interoperable EHRs into consideration in future years and will consider how we can better encourage hospitals to engage with dialysis facilities to share patient information as appropriate.

Comment: A commenter supported adding the MedRec measure to the QIP starting with

PY 2022. The commenter noted that medication reconciliation is an example of a safety intervention that is effective in research settings but is difficult to implement successfully in general practice. The commenter stated that several reports show that dialysis patients have frequent discordant medication regimens and stated that medication reconciliation is the process for keeping an accurate medication list. The commenter noted that no information supports that medication reconciliation alone improves health outcomes and that it should be combined with medication assessment/comprehensive medication review focused on indication, effectiveness, and safety of drugs as well as patients' convenience. The commenter also stated that multidisciplinary medication therapy management programs that provide both medication reconciliation and review services to dialysis patients have been shown to reduce hospital readmissions. In addition, the commenter recommended that CMS combine medication reconciliation with a comprehensive medication review.

Response: We thank the commenter for its support. We will take its suggestions into consideration in future years.

Comment: A commenter generally supported our proposal to adopt the MedRec measure but requested that we define "eligible professional" as any clinician who can perform medication reconciliation in accordance with state licensure requirements. The commenter noted that this could include registered nurses (RNs), advance practice registered nurses (APRNs), and physician assistants. The commenter also supported the exclusion of patients who receive fewer than 7 hemodialysis treatments in a reporting month. Another commenter requested that we consider adding licensed practical nurses (LPNs) to the measure's "eligible professionals" list to avoid causing burden to its RN staff.

Response: We thank the commenters for their feedback. We proposed to define “eligible

professional” by incorporating the NQF’s definition of that term (physicians, RNs, APRNs, PAs, pharmacists, and pharmacy technicians).²⁰ However, in response to this feedback, we are finalizing the MedRec measure with an expanded definition of “eligible professional.” Specifically, we will remove the reference to RNs and replace that reference with “nurses.” This change will allow all types of nurses, including LPNs, to perform medication reconciliations within the scope of their licenses.

Comment: A commenter supported medication reconciliation in concept, acknowledging that medication reconciliation is a critical safety issue for dialysis patients, but expressed concern about the continued reliance on measures of processes. The commenter was worried that process measures can be burdensome for providers to report. The commenter suggested that CMS consider addressing this topic through Medicare's conditions for coverage for ESRD facilities rather than adopting the measure.

Response: We disagree with the commenter’s recommendation to address medication reconciliation through Medicare’s conditions for coverage for ESRD facilities rather than adopting the MedRec measure in the QIP. Given that medication reconciliation is currently a gap area in QIP’s measure set and is an important patient safety issue for the ESRD patient population, we believe that the benefits of the measure’s inclusion outweigh the providers’ reporting burden.

Comment: Commenter suggested adding an exclusion to MedRec for patients in their first month of treatment or transient patients.

Response: We disagree with the commenter’s suggestion. It is important to engage in medication reconciliation during a patient’s first month or their first visit because medication

²⁰ See <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/NQF-2988-Patients-Receiving-Care-at-Dialysis-Facilities.pdf>.

errors are more likely to occur during care transitions.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt the MedRec measure for the ESRD QIP beginning with PY 2022, with one change; as previously discussed. We are finalizing the definition of “eligible professions” to include all nurses, instead of RNs only.

2. Performance Period for the PY 2022 ESRD QIP

We proposed 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 invited comment on this proposal. However, we did not receive any comments specific to the PY 2022 ESRD QIP’s performance period. We are therefore finalizing the PY 2022 performance period as proposed.

3. 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. 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 proposed 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 also proposed to apply these performance standards to all clinical measures we use for the ESRD QIP in future payment years. We invited comment on these proposals.

At the time of the CY 2019 ESRD PPS proposed rule's publication, we did not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures because we did not yet have sufficient CY 2018 data. We stated our intent to publish these numerical values, using CY 2018 data received in CY 2018 and the first portion of CY 2019, in the CY 2019 ESRD PPS final rule. However, we erred in that statement, and should have said that we would publish those numerical values in the CY 2020 ESRD PPS final rule, as we would not be able to collect any data from the first portion of CY 2019 prior to the CY 2019 ESRD PPS final rule's publication.

We sought comments on the proposed performance standards for clinical measures. However, we did not receive any comments and are finalizing these performance standards as proposed without change.

b. 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). In the CY 2019 ESRD PPS proposed rule (83 FR 34346), we proposed 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 also proposed 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 invited comments on these proposals. However, we did not receive any public comments and are finalizing the proposed performance standards as proposed for PY 2022 and future payment years.

4. Scoring the PY 2022 ESRD QIP and Subsequent Years

a. Scoring 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). In the CY 2019 ESRD PPS proposed rule (83 FR 34346), we proposed 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 payment years.

We invited public comments on this proposal. However, we did not receive any public comments and are finalizing our policy to score facility performance on clinical measures based on achievement as proposed for PY 2022 and future payment years.

b. Scoring 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). In the CY 2019 ESRD

PPS proposed rule (83 FR 34346), we proposed that for the PY 2022 ESRD QIP, we would 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). We stated that 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 proposed to use this same methodology for scoring the PPPW measure proposed in section IV.C.1.a of the CY 2019 ESRD PPS proposed rule. Finally, we proposed to continue this policy for subsequent years of the ESRD QIP.

We invited public comments on this proposal. However, we did not receive any public comments and are finalizing our policy to score facility performance on clinical measures based on improvement as proposed for PY 2022 and future payment years.

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). In the CY 2019 ESRD PPS proposed rule (83 FR 34346 through 34347), we proposed 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 also proposed 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):

$$\frac{(\# \text{ patient-months successfully reporting data})}{(\# \text{ eligible patient-months})} * 12 - 2$$

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 through 10. We also proposed to score facilities using this methodology for subsequent years of the ESRD QIP.

We invited public comment on these scoring proposals. However, we did not receive any public comments specific to scoring facilities' performance on reporting measures. Therefore, we are finalizing our policies for scoring facility performance on the Clinical Depression Screening and Follow-up and Ultrafiltration Rate reporting measures, as proposed, for PY 2022 and future payment years. We are also finalizing our proposal to score the MedRec measure and will apply that scoring methodology to PY 2022 and future payment years.

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 proposed to use this scoring methodology for the PY 2022 ESRD QIP and subsequent years.

We invited comments on this scoring proposal. However, we did not receive any public comments and are finalizing our policy to score facility performance on the ICH CAHPS reporting measure as proposed.

5. Weighting the Measure Domains TPS for PY 2022

For PY 2022, we proposed in the CY 2019 ESRD PPS proposed rule (83 FR 34347) to continue use of the domain weights proposed for PY 2021, 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 proposed 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 proposed 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 proposed to assign the proposed MedRec measure to the Safety Domain, with a weight of 4 percent of the TPS (see Table 21). To accommodate the addition of the new MedRec measure to the Safety Domain without having to adjust the domain’s overall weight, we proposed 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 21: 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 the CY 2019 ESRD PPS proposed rule (83 FR 34347), we proposed 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. We also stated that if that proposal is finalized, we would apply it to PY 2022 and subsequent payment years.

We invited comments on these proposals.

The comments and our responses to the comments on our weighting proposals are set forth below.

Comment: A commenter was concerned that we had not fully considered the reporting burden associated with each quality measure when reweighting for PY 2022, specifically with respect to the NHSN Dialysis Event Reporting measure. The commenter stated that dialysis facilities undertake significant effort to report data for that measure, and that its importance to care quality measurement means that its weight should not be reduced as proposed. The commenter requested that we reconsider lowering the Dialysis Event Reporting measure's weight.

Response: We disagree with the commenter's concern that the NHSN Dialysis Event reporting measure's proposed PY 2022 weight is too low. The measure's weight reflects the Meaningful Measures priorities and our preferred emphasis on weighting measures that directly impact clinical outcomes more heavily than other measures.

Final Rule Action: After considering the public comments received, we are finalizing our domain and measure weighting policy for PY 2022 as reflected in Table 22. These measure weighting changes are consistent with those finalized for PY 2021 (and thus incorporate the commenters' feedback on the PY 2021 domain weighting) (see Table 17) and accommodate the new measures that we are finalizing for PY 2022, which we are placing in the Care Coordination

Domain (PPPW measure) and the Safety Domain (MedRec measure).

TABLE 22: Finalized Measure Domain Weighting for the PY 2022 ESRD QIP

Measures/Measure Topics by Subdomain	Measure Weight as Percent of TPS (Finalized for PY 2022)
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN	
ICH CAHPS measure	15.00%
	15.00% of TPS
CARE COORDINATION MEASURE DOMAIN	
SRR measure	12.00%
SHR measure	12.00%
PPPW measure	4.00%
Clinical Depression and Follow-Up reporting measure	2.00%
TOTAL: CARE COORDINATION MEASURE DOMAIN	30% of TPS
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	9.00%
Vascular Access Type measure topic*	12.00%
Hypercalcemia measure	3.00%
STrR measure	10.00%
Ultrafiltration Rate reporting measure	6.00%
	40% of TPS
SAFETY MEASURE DOMAIN	
MedRec measure	4.00%
NHSN BSI clinical measure	8.00%
NHSN Dialysis Event reporting measure	3.00%
TOTAL: SAFETY MEASURE DOMAIN	15% of TPS

6. Eligibility Requirements 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). In the CY 2019 ESRD PPS proposed rule (83 FR 34347), we proposed to continue use of these minimum data policies for the PY 2022 ESRD QIP measure set and in subsequent years. We also proposed 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 invited comment on these eligibility proposals.

The comments and our responses to the comments on our proposal are set forth below.

Comment: A commenter stated that there is a lack of consistency in the minimum data requirements and a lack of clear and empirical rationale for the small facility adjuster. The commenter suggested that CMS adjust measures to yield a result with a reliability statistic of at least 0.70, which the commenter believed is consistent with how NQF assesses its evaluation of measures. The commenter stated that this change would prevent small facilities from receiving scores with random variability.

Response: We thank the commenter for this feedback. We would like to clarify that under our current policy, we will use a small facility adjuster threshold of 11 through 25 eligible patients for the PPPW measure. We would also like to clarify that NQF does not employ a specific standard for a quality measure's reliability statistic. We have adopted minimum data requirements and the small facility adjuster to accommodate the different types of quality measures that we have adopted in the ESRD QIP and the different types of data collected for them. We have concluded that different minimum data thresholds are appropriate. We further believe that the small facility adjuster appropriately ensures that small facilities do not receive measure scores with random variability. However, we will continue to examine this issue.

Final Rule Action: After considering public comments received, we are finalizing our eligibility policies, as proposed. Table 23 provides a summary of these eligibility policies for the PY 2022 ESRD QIP measure set and future years.

TABLE 23: Eligibility Requirements for the PY 2022 ESRD QIP Measure Set

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type:	11 qualifying patients	N/A	11-25 qualifying patients

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Long-term Catheter Rate (Clinical).			
Vascular Access Type: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
NHSN Bloodstream Infection (Clinical)	11 qualifying patients	Before October 1, 2019	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before October 1, 2019	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1, 2019	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1, 2020	N/A
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before April 1, 2020	N/A
Medication Reconciliation (Reporting)	In-center patients who receive 7 or more hemodialysis treatments in the facility during the reporting month	Before October 1, 2019	N/A
Percentage of Prevalent Patients Waitlisted (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

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. Requirements Beginning with the PY 2024 ESRD QIP

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

In the CY 2019 ESRD PPS proposed rule, we proposed 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 1 year of the date when dialysis is initiated. We stated that we believe this measure would encourage facilities to more rapidly evaluate patients for transplant and coordinate the waitlisting of those patients.²¹ 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 proposed to introduce the SWR measure for PY 2024 rather than PY 2022 because the proposed SWR

²¹ 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.

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 proposed 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 final rule, and to score the two measures accordingly as a measure topic. We note also that there are currently no

NQF-endorsed 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 invited comments on this proposal. Because many public commenters addressed the PPPW and SWR measures together, we addressed some comments on the SWR measure in section IV.C.1.a of this final rule.

Additional comments and our responses to the comments on our proposal to add the SWR measure to the ESRD QIP measures set are set forth below.

Comment: Some commenters opposed our proposal to adopt the SWR measure, stating that the measure is limited in its action ability by the dialysis center because the waitlist decision is made by the transplant center, not the dialysis facility. One commenter noted that incident dialysis patients not listed for transplants may be more complex or have comorbidities that make them ineligible for the waitlist during the first year. The commenter also stated that the measure could create a perceived incentive to start advanced chronic kidney disease (CKD) patients on dialysis earlier because it would not recognize dialysis units' role in pre-education and care coordination for patients who have received a pre-emptive transplant. One commenter noted that disparities remain an issue in the pediatric population, and that facilities' ability to waitlist or coordinate transplant waitlists is limited. The commenter reiterated its view that a patient-centered educational effort would be more appropriate for use in the QIP than the SWR measure. The commenter also recommended us to revisit and expand the measure's exclusion criteria if it decides to finalize the measure.

Response: As we noted with respect to the PPPW measure above, waitlisting for transplantation is the culmination of a variety of preceding activities. These include (but are not

limited to) education of patients about the transplant option, referral of patients to a transplant center for evaluation, completion of the evaluation process and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis facilities. Although some aspects of the waitlisting process may not entirely depend on facilities, such as the actual waitlisting decision by transplant centers, or a patient's choice about the transplantation option, these can also be nevertheless influenced by the dialysis facility. The waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis facilities. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis facilities can be and are already making towards access to transplantation, to the benefit of the patients under their care.

With respect to the commenter's concern about potentially creating an incentive for nephrologists to start advanced ESRD patients on dialysis earlier, we believe that dialysis facilities have a responsibility to ensure that they furnish proper care to their patients.

Comment: A commenter opposed our proposal to adopt the SWR measure, stating that its adoption seems to conflict with stricter outcome guidelines that we have adopted for transplant centers. The commenter also suggested that it would be helpful if we developed CROWNWeb software changes proactively for new quality measures, as the SWR measure could require significant resources and time to report.

Response: We will develop CROWNWeb software changes as proactively as is feasible for new measures to ensure that dialysis facilities are able to understand those changes and report their quality measure data as promptly and effectively as possible.

However, as we discuss further below, we are not finalizing the SWR measure at this

time, so such changes will not be necessary. We disagree that the SWR measure's adoption would conflict with guidelines that we have adopted for transplant centers, however, as the goal of the measure is to ensure that patients are appropriately waitlisted for transplants and not that they must receive transplants. While we appreciate that transplant centers must focus on clinical outcomes, the purpose of adopting a measure of transplant waitlisting for dialysis facilities is not to encourage unnecessary transplants but to ensure that patients can receive the benefit of that treatment modality when appropriate.

Comment: A commenter expressed concern that it is unable to discern how widely reliability varies across the spectrum of facility sizes because CMS has not provided stratification of reliability scores by facility size for the PPPW measure and the SWR measure. The commenter expressed concern that the reliability for small facilities may be significantly lower than the overall inter-unit reliabilities (IURs), as the commenter explained is the case with other CMS standardized ratio measures. The commenter expressed special concern for the SWR, which has an IUR of 0.6 and is considered moderately reliable by statistical convention. The commenter suggested that CMS demonstrate reliability for all facilities by providing data by facility size.

Response: We acknowledge the commenter's concern about smaller facilities. For each measure respectively, facilities with fewer than two expected events (SWR) or 11 eligible patients (PPPW) are not included in the respective measure calculations.

In regards to the specific comment about IUR, the IUR for these measures is "moderate" and similar to or higher than many other population-based measures used in public reporting and VBP programs. IUR is a general expression of the distribution of within and between facility variance in the population of facilities. The formula for IUR includes a term for patient number,

so IUR will always be lower for smaller facilities and higher for larger facilities regardless of the measure. The IUR for all facilities is what the NQF uses to evaluate the measure, so we believe including values stratified by different facility size would be misleading for the public. For public reporting, our method for identifying outlier facilities utilizes the empiric null approach, which adjusts for flagging rates by facility size; that is, smaller facilities that have more extreme outcomes compared to other smaller facilities will be flagged.

Comment: A commenter expressed a preference for normalized rates or year-over-year improvement in rates for the SWR measure instead of a standardized ratio, suggesting that comprehension, transparency, and utility to stakeholders is superior with a scientifically valid rate methodology.

Response: Placing a facility's risk adjusted rate in context requires reference to a standard rate that applies to the population as a whole. The ratio estimate that we proposed is the ratio of the facility adjusted rate to the standard rate. The ratio is also a scientifically valid approach and, in our experience, most people find the ratio to be understandable and to sufficiently convey the rates. Most regression analyses (of binary or count responses) in the clinical and epidemiologic literature are based on ratios. Ratio measures are well accepted in the published literature. Additionally, the risk-adjustment approach currently used for the STrR, SHR, SRR, and SWR measures are based on indirect standardization which also forms the basis of many measures implemented in the ESRD QIP and other CMS quality reporting and VBP programs, and we believe that this approach leads naturally to a standardized ratio. This ratio compares the rate for this facility with the national rate, having adjusted for the patient mix and as such is relatively straightforward.

Comment: A commenter raised concerns about the validity of CMS Form 2728--the

source for 11 of the SWR's incident comorbidities--and urged CMS to work with the community to assess this issue in further detail.

Response: We disagree with the commenter's concerns about the validity of CMS form 2728. Comorbidities reported on this form have been found to be useful predictors of mortality, suggesting that the most salient comorbidities are reported.²² The comorbidities from the CMS Form 2728 included in the SWR model were chosen based on their association with first year mortality. Additionally, we believe that it is reasonable to expect dialysis facilities to have an awareness of patient comorbidities at incidence. When dialysis facilities receive an intake call, they receive an extract of the patient's chart, which includes current conditions/comorbidities. Facilities should be reviewing that chart before accepting a patient. Dialysis facilities also attest to the accuracy of the information reported on the 2728 prior to submitting the form to CMS.

Comment: A commenter requested information as to why the proposed SWR measure does not include an exclusion for patients with a previous transplant. The commenter noted that during the NQF Renal Standing Committee's consideration of the SWR measure, CMS said that this exclusion would be present in the measure's specifications.

Response: We thank the commenter for their feedback. The following exclusion is incorporated into the denominator definition for the PPPW and SWR measures:

- Preemptive patients: patients at the facility who had the first transplantation prior to the start of ESRD treatment; or were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.

We will modify the technical specifications to make sure that the exclusion is fully and clearly stated in the posted materials to prevent any misunderstanding.

²² Wolfe et al., 2000; Ashby et al., 1998; Roys et al., 1999

Comment: A commenter raised concerns about the exclusion of patients waitlisted prior to the start of dialysis, noting that this may be a disincentive to those nephrologists actively attempting to enable preemptive transplantation as a viable alternative to dialysis. The commenter recommended that CMS remove that exclusion if the SWR measure is included in the final rule.

Response: We thank the commenter for this concern. However, as noted above, we are not finalizing the SWR measure at this time. We will consider addressing this exclusion if we propose to adopt the SWR measure in the future.

Final Rule Action: After considering the public comments that we have received, we are not finalizing our proposal to add the SWR measure to the Program.

2. Performance Period for the SWR Measure

Because the SWR measure is calculated using 36 months of data, we proposed 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 continue to believe that a 36-month performance period for the SWR measure would enable us to calculate sufficiently reliable measure data for the ESRD QIP.

Final Rule Action: We are not finalizing the SWR measure, therefore, we are not finalizing the performance period for the SWR measure.

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

We stated that, if finalized, 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.

We also stated that at the time of the CY 2019 ESRD PPS proposed rule's publication, we did not have the necessary data to assign numerical values to the performance standards for the SWR measure, because we did not yet have data from CY 2017 through CY 2020.

We welcomed public comments on the performance standards for the SWR measure. However, we did not receive any public comments specific to the SWR measure's performance standards.

Final Rule Action: As discussed above, we are not finalizing the SWR measure, and we are therefore not finalizing the performance standards for the SWR measure.

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. More information on the different rounds of competitions and general information regarding the CBP is available on the following website:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/DMEPOSCompetitiveBid/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html) 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 currently 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. This calculation is reflected in the current definition of composite bid under existing § 414.402, which we are further modifying in this final rule. 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.

Currently, 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 bids submitted and accepted from 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 discussed 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 SPAs 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 SPAs 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 that final rule (81 FR 77931). The bid bond requirement was mentioned in the background section of the proposed rule because bid bond forfeiture is tied to composite bids under the DMEPOS CBP, and this rule finalizes a change to how composite bids are defined and implements lead item pricing under the DMEPOS CBP (83 FR 34350).

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.

Section 1847(b)(6)(A) of the Act provides 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. Except in limited circumstances, 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 existing regulation at § 414.412, which we are modifying in this final rule, 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 and conditions for awarding contracts under section 1847(b)(2) of the Act and § 414.414, which we are also modifying in this final rule. 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

Currently, 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 existing § 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. In accordance with § 414.402, item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category. Item weights are used to reflect the relative market importance of each item in the product category. Table 26 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 26: 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 27 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 27: 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
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 2 years, trended forward to the contract period. Table 28 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 28, 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. In accordance with existing § 414.414(e)(6), all suppliers and networks whose composite bids are less than or equal to the pivotal bid for the product category, and that meet the supplier eligibility requirements in § 414.414(b) through (d) are selected as winning suppliers. Suppliers 1, 4, 6, 9, 5, 11 and 7 are selected as winning suppliers in the example below in Table 28. The composite bids for suppliers 10, 8, 3, and 2 are above the pivotal bid, so these suppliers are not selected as winning suppliers for the product category and are eliminated from the competition.

TABLE 28: Determining the Pivotal Bid for Product Category Point where beneficiary demand (1,800) is met by supplier capacity

Supplier Number¹	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 ways 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 maximum 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 ways 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). Under existing § 414.416, we finalized use of the median of winning bids for each item in each CBA to determine the SPA for each item in each CBA. The individual items within each product category 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 29 illustrates the current method.

TABLE 29: Median of the Winning Bids Methodology

Item	A	B	C	Composite Bid
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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 (median A and B)	\$2.00	\$3.00	\$3.00	\$2.50
Supplier 5 bid (median C)	\$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	

For a more complete discussion of this methodology, see section V.C of the CY 2019 ESRD PPS DMEPOS proposed rule.

D. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on DMEPOS CBP

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed two reforms to simplify the DMEPOS CBP, eliminate the possibility for price inversions, and ensure the long term sustainability of the program. We proposed lead item pricing for all product categories under the DMEPOS CBP and calculation of SPAs using maximum winning bids for lead items. We proposed to amend §§ 414.402, 414.412, 414.414, and 414.416 to add and revise certain existing definitions, and revise the methodology for the calculation of SPAs and the evaluation of bids under the CBP to reflect and establish a lead item pricing methodology.

We received approximately 258 public comments on the proposed rules from manufacturers, suppliers, accrediting organizations, clinician organizations, Congress, government entities, hospital associations, beneficiary and industry representative groups, and other individual stakeholders. Several comments were outside the scope of this rulemaking.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for DMEPOS CBP.

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

In the CY 2016 ESRD PPS final rule (81 FR 77945), we established alternative rules for submitting bids and determining SPAs for certain groupings of similar items with different features under the DMEPOS CBP. As discussed in that 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 price inversions 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 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, transcutaneous electrical nerve stimulation (TENS) devices, support surface mattresses and overlays and seat lift mechanisms. We consider the price of an item to be “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 CY 2016 ESRD PPS final rule (81 FR 77945 through 77949).

In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34354 through 34359), we proposed to establish a lead item pricing methodology for all items and all product categories under the DMEPOS CBP. We proposed that the methodology would apply to all items in the product category. We also proposed that the lead item would be identified based on total national allowed charges. We proposed that the lead item pricing methodology 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 referred to this proposed policy as “lead item pricing” rather than “lead item bidding.” We proposed to implement lead item pricing and change the methodology for establishing SPAs under the CBP for a number of reasons which are discussed in more detail in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34349). We stated that we believed that lead item pricing would greatly reduce the complexity of the bidding process and address all price inversions we have already identified as well as potential future price inversions for other items. It would also reduce 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.

We refer readers to section V.D.2 of the CY 2019 ESRD PPS DMEPOS proposed rule for examples of how this pricing method would work.

We proposed to revise the current definition for “composite bid” under § 414.402 to mean “the bid submitted by the supplier for the lead item in the product category.” As discussed in section V.A of this final 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 proposed 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 noted 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 (83 FR 34355). 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).

Currently under existing § 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 D.C. where Medicare beneficiaries reside and can receive covered DMEPOS items and services. We proposed 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 proposed to replace the “lead item” description in § 414.412(d)(2) and “total nationwide allowed services” definition with a new definition of “lead item” in § 414.402 (83 FR 34414). We believed 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. We also believed the item with the most allowed services is not always the item that generates the most revenue for the supplier.

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 proposed 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 (83 FR 34414).

Finally, we proposed 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 specifies 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 proposed to specify 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 (83 FR 34414).

2. Calculation of single payment amounts using maximum winning bids for lead items

We proposed to revise § 414.416 to change the methodology for calculating SPAs under the CBP. We proposed to base the SPA for the lead item in each product category and CBA on the maximum or highest amount bid for the lead item by suppliers in the winning range as illustrated in Table 30. 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, D.C., 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, since 2015 is the last year the fee schedule amounts were not adjusted based on information from the CBP, 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). Under the proposed revised definition of composite bid, each supplier's bid for the lead item would be their composite bid. The proposed methodology of using the maximum winning bids to establish SPAs is illustrated in Table 30. 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 a more complete discussion of the rationale for this methodology, see section V.D.2 of the CY 2019 ESRD PPS DMEPOS proposed rule.

TABLE 30: 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

Finally, we invited 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 solicited feedback that we could consider in potentially adjusting the size and boundaries of CBAs for future competitions. We noted there are currently nine CBAs with more than 7,000 square miles: Phoenix-Mesa-Scottsdale, Arizona; Boise City, Idaho; Dallas-Fort Worth-Arlington, Texas; Riverside-San Bernardino-Ontario, California; Houston-The Woodlands-Sugar Land, Texas; Bakersfield,

California; Salt Lake City, Utah; San Antonio-New Braunfels, Texas; and Atlanta-Sandy Springs-Roswell, Georgia.

The comments and our responses to the comments on our proposals are set forth below.

Comment: Many commenters supported the proposal to establish lead item pricing for all items and product categories in the CBP because it simplifies the bidding process and eliminates price inversions. Some commenters supported the proposal to establish lead item pricing for all items and product categories in the CBP, but only if the product categories were discrete categories of like items that are generally provided together to address a beneficiary's medical needs. The commenters recommended that large product categories with varying items (such as standard mobility equipment) be subdivided. Some commenters recommended that some product categories (such as power wheelchairs) include subcategories with lead items for each subcategory (such as power wheelchair bases, batteries, etc.). One commenter representing suppliers of oxygen and oxygen equipment was concerned that maintaining the term "composite bid" could lead to confusion, but indicated that they are committed to working with CMS to ensure that defining this term to mean the lead item bid is well understood by suppliers.

Response: We appreciate the support for this proposal. Although product categories are not defined through rulemaking, we will be taking into consideration the various product category recommendations, including the recommendation to structure product categories to ensure that they contain discrete categories of like items that are generally provided together to address a beneficiary's medical needs, when implementing future rounds of competition under the CBP. We appreciate the one commenter's willingness to educate suppliers regarding the revised definition for composite bid.

Comment: One commenter expressed concern that the lead item pricing method

effectively makes it possible for suppliers to submit bids on lead items without verifying they can furnish the entire category. The commenter recommended that when awarding contracts, CMS consider not only bid price, but also a supplier's range of available supplies and devices.

Response: We do not agree. Suppliers are educated at the start of each round of competitive bidding that they are responsible for furnishing all items in the product category for which they are submitting bids. Under lead item pricing, which we are adopting in this final rule, we will educate suppliers that their bid for the lead item is a bid for furnishing all items in the product category. We will also educate suppliers on how the payment amounts for the items in the product category will be established based on the maximum winning bid for the lead item. If the product categories are discrete categories of like items as commenters have suggested, a supplier that can furnish the lead item in the product category should have the capacity to furnish all other items in the product category as well. For example, if the supplier bids in the power mobility devices product category, the supplier would need to be accredited and meet the quality standards applicable to power mobility devices, namely part II of Appendix B of the Medicare DMEPOS Quality Standards. If the supplier meets these standards, then they should have the ability to furnish all of the different types of power mobility devices. If a supplier historically has furnished certain types of power mobility devices, such as standard weight captains chair products, and not others, such as heavy duty sling seat products, it should be relatively easy for the supplier to purchase the additional types of power mobility devices and deliver those items as well. It is important to note that under competitive bidding, CMS ensures that a sufficient number of contract suppliers are available to meet the expected demand for a product in each CBA. In accordance with section 1847(b)(2)(A) of the Act and § 414.414, a supplier cannot be awarded a contract unless they meet certain financial standards that ensure they have an ability to

expand their capacity beyond their historic capacity. The amounts suppliers bid and the capacity they report are reviewed to ensure they are bona fide. In addition, a special analysis of the supplier's reported capacity is performed and the supplier's reported capacity is adjusted to their historic levels of performance if there is any question regarding their ability to expand their capacity. CMS awards contracts to a sufficient number of contract suppliers to meet projected demand in each CBA.

The supplier's bid for the lead item would reflect the cost of furnishing the various types of power mobility devices and related accessories in the product category. Even if the current product categories are maintained as is, a supplier would have to be able to furnish all of the items in the product category in order to be considered for a contract. Under the terms of the DMEPOS CBP contracts, a contract supplier must furnish every item in the product category for which it was awarded a contract. All suppliers are educated at the time of bidding that in accordance with § 414.422(e)(1), a contract supplier must 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. Suppliers are made aware of this requirement and understand that they must have the capacity to furnish every item in the product category if they want to be a contract supplier. If the supplier does not comply with this regulation or a term of their contract, then the supplier would be in breach and CMS could terminate the contract.

Comment: One commenter expressed concern that it would be inaccurate to assume that the bid rate for a single lead item is representative of the entire product category and believes the ratios that would be used to price the non-lead items do not accurately reflect the difference in cost of the items in the product category because of lack of consistency in how the fee schedule

amounts for the items were established (that is, average reasonable charges for some items and gap-filling using supplier price lists for other items). Another concern was related to the supplier's inability to control the bid price of non-lead items without adjusting their lead item bid amount. For example, if the supplier is willing to accept payment for the lead item at an amount that is 50 percent below the historic, unadjusted fee schedule amount for the lead item, but is not willing to accept that large of a payment reduction for a non-lead item, the supplier would not be able to submit a bid for the lead item that is 50 percent below the historic, unadjusted fee schedule amount for the lead item. A commenter also mentioned that there could be little to no commonality in the manufacturing processes between lead item and non-lead items, which could lead to excessive or discounted payments for non-lead items.

Response: We understand that the inability of the supplier to submit specific bid amounts for non-lead items in order to determine the payment amounts for these items is a cost or negative aspect of lead item pricing. However, we believe that the benefits associated with lead item pricing outweigh this cost. Lead item pricing would greatly reduce the complexity of the bidding process and address all price inversions we have already identified as well as potential future price inversions for other items. It would also reduce the burden on suppliers since they would no longer have to submit bids for numerous items in a product category. Under lead item pricing, suppliers will be educated on how the payment amounts for the items in the product category will be established based on the maximum winning bid for the lead item, and that they should consider their costs for furnishing all items in the product category in formulating their bid for the lead item. In the example provided above, a supplier that cannot accept a payment reduction of 50 percent for a non-lead item would need to factor this fact into what they bid for the lead item, because the bid for the lead item would also represent their bid for furnishing all of

the items in the product category. They may have to bid an amount that is higher than the amount they would bid if they were bidding for the lead item alone in order to factor in the cost of furnishing all of the other items in the product category. If the historic differences in the fees for the various items in the product category do not align well with the actual differences in the cost of the items, the supplier will need to take this into consideration when submitting their bid for the lead item. The ratios that will be used to price the non-lead items are based on the historic differences in the fee schedule amounts for the items, and we do not think that these historic ratios inaccurately reflect the relative differences in the cost of the items. Rather, the ratios usually follow a logical pattern. For example, the historic fees for manual hospital beds are lower than the historic fees for semi-electric hospital beds, and the historic fees for manual hospital beds without side rails are lower than the historic fees for manual hospital beds with side rails. Suppliers are given an opportunity, by bidding for the lead item, to control the minimum amount (that is, under lead item bidding, suppliers are paid at least what they bid or higher) that they would be paid for any non-lead item, as illustrated in the supplier non-lead item bidding example directly above. Suppliers must take this and other factors into consideration when determining how much to bid based on what they are willing to accept as payment for the items in the product category as a whole. Again, we believe that the benefits associated with lead item pricing, as explained above and in the CY 2019 ESRD PPS DMEPOS proposed rule, outweigh the cost of less flexibility in setting payment rates for non-lead items. We are not sure what point the commenter was making regarding little to no commonality in the manufacturing processes between a lead item and non-lead items, and how this could lead to excessive or discounted payments for non-lead items. We will educate suppliers regarding how their bid for the lead item is used to generate the payment amounts for the non-lead items and that they

should ensure that the payment amounts for all of the other items in the product category, which are established based on their bid for the lead item, would be sufficient to cover their costs for furnishing all of the items in the product category in the CBA.

Comment: A few commenters suggested that bids from suppliers added to meet the small supplier target be included in the calculation of the SPAs.

Response: We appreciate the comment, however, we do not agree. The small supplier target was established due to the statutory mandate to ensure that small suppliers are considered for participation under the CBP. Small suppliers that are offered contracts after the pivotal bid is determined are not needed to meet projected demand. We do not think that payment to suppliers needed to meet projected demand should be based on higher bids from suppliers that are not needed to meet projected demand.

Comment: Several commenters offered suggestions on how to determine the capacity of bidding suppliers to meet projected demand for items and services. For example, some commenters suggested that the actual historic capacity of suppliers should be used and should not be adjusted. One commenter suggested capping assumed supplier capacity at 25 or 33 percent of total projected demand. Many commenters recommended that the process of determining projected demand and supplier capacity should be transparent and that the determinations should be made publically available to ensure the bid evaluation is accurate.

Response: As a part of the competitive bidding program, we strive to ensure a sufficient number of contract suppliers are available to meet the expected demand for a product in each CBA. As a part of the bid evaluation process, bidders are required to report their capacity to furnish bid items on the bid form. CMS awards contracts to a sufficient number of contract suppliers to meet projected demand in each CBA. CMS purposely sets a high demand target by

increasing historic utilization using two trending factors (national growth in DME utilization and change in enrolled beneficiaries in the CBA) rather than just one. In addition, if the change in enrolled beneficiaries in a CBA is negative, CMS does not decrease the demand target number based on this negative trend in the beneficiary population in the area and still increases the number based on the national growth in utilization for the item. In addition, the projected demand for DME items is not reduced based on the number of items that would likely be furnished by grandfathered suppliers, which typically furnish approximately 15 percent of rented DME items and related accessories. Each supplier's capacity is capped at 20 percent of total projected demand, and each supplier's capacity is evaluated, scrutinized and adjusted if necessary to ensure that they are not relied upon to furnish more items and services than they can based on their financial strength and ability to expand their historic capacity. This approach to estimating demand and capacity has worked well over the past eight years to ensure that a sufficient number of contracts are awarded under the CBP. We thank the commenters for their suggestions and will take them into consideration.

Comment: In response to our request for feedback about the risk that under our proposed methodology, the maximum winning bid could be an outlier bid that is much higher than the other winning bids, most commenters generally felt that this risk was minimal, some suggested, as long the product categories are evaluated in detail. Another commenter believed the risk was minimal because the lead item SPA is capped at the historical fee schedule amount. One commenter suggested an approach to limit maximum winning bids that are more than double the next highest winning bid. Under the suggested approach, the average of the maximum winning bid and the next highest winning bid would be used to establish the lead item SPA. Another commenter suggested we monitor the range of winning bids in each product category to assess

risks in the next round of bidding. One commenter believed that SPAs based on the maximum winning bids could result in excessive payment rates if beneficiary demand is overestimated or supplier capacity is underestimated.

Response: We thank the commenter that provided a suggestion to address the scenario of an outlier bid. At this time, however, we have no reason to believe this will be a problem and have set certain limits under the CBP. For example, the SPA must be less than or equal to the amount that would otherwise be paid. CMS may only award a contract to a bidder if it finds that the total amounts to be paid to suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. CMS will monitor the program and make changes in the future if such situations occur. We agree that basing the SPAs on maximum winning bids could result in excessive payment rates if beneficiary demand is overestimated or supplier capacity is underestimated. As explained in response to the preceding comment, CMS inflates historic demand by double trending the numbers, does not reduce the number for DME items to account for grandfathered suppliers, and scrutinizes and adjusts supplier capacity to ensure that a sufficient number of contracts are awarded under the CBP. To the extent that more contracts are awarded than necessary as a result of this process, this could result in higher payment amounts than would otherwise be paid if fewer contracts were awarded. However, we note that this is true regardless of whether SPAs are based on maximum winning bids or the median of winning bids. We intend to closely monitor the impact of the new pricing methodology to determine if it results in excessive payment rates and whether the process for estimating demand and capacity should be revised to eliminate excessive payment rates.

Comment: Regarding bid surety bonds, one commenter suggested that a supplier should forfeit the bond if their bid is at or below the maximum winning bid for the lead item, rather

than the median of the winning bids for the lead item, and the supplier does not accept the contract offer. One commenter recommended that any winning bidder that does not accept a contract offer should forfeit the bid surety bond.

Response: We appreciate the suggestions but the statute at section 1847(a)(1)(H)(i) of the Act specifically mandates forfeiture of a bidding supplier's bid bond in cases where the supplier's composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the SPAs and the entity does not accept the contract offered.

Comment: Most commenters provided negative feedback in response to our solicitation of comments on whether nine large CBAs should be subdivided into smaller size CBAs to create more manageable service areas for suppliers. The commenters contended that subdividing the CBAs would result in increasing administrative complexity and costs. The commenters discussed increased costs to prepare bids for more geographic areas, including obtaining more bid surety bonds for more geographic areas. Also, the commenters discussed increasing complexity for referrals, prescribers, and beneficiaries to coordinate furnishing DMEPOS items with different contracted suppliers based on more CBAs and the home zip code of the Medicare beneficiary. One commenter stated that the CBAs as currently set are appropriate for defining markets in which the costs are aligned and subdividing the CBAs could reduce the economies of scale achievable in these areas. Also, the commenters expressed concern that subdividing CBAs could lead to substantially different payment amounts for similar products furnished in close proximity geographic areas. To further specify, several commenters did not support subdividing the CBA areas for Atlanta-Sandy Springs-Roswell, GA MSA, the Houston-The Woodlands-Sugar Land, TX MSA and Boise City, ID MSA. In contrast, one commenter provided positive feedback to our solicitation on whether certain large CBAs should be subdivided into smaller

size CBAs to create more manageable service areas for suppliers for the Riverside-San Bernardino-Ontario CA MSA. Also commenters did not provide specific feedback to our solicitation regarding the following CBAs: Phoenix-Mesa-Scottsdale, Dallas-Fort Worth-Arlington, Bakersfield, CA, Salt Lake City, Utah, and San Antonio-New Braunfels, Texas. Some commenters recommended that CMS consult with the suppliers in the specific CBA before finalizing a subdivision of a CBA. One commenter described an example that if the San Francisco-Oakland-Fremont, CA CBA is subdivided beneficiaries could experience access problems in Fremont but not San Francisco. The commenters recommended further consideration for subdividing areas should be considered from both contracting and oversight perspectives.

Response: We appreciate the range of the comments we received. We will consider these comments carefully as we contemplate future policies.

Final Rule Action: After consideration of comments received on the CY 2019 ESRD PPS DMEPOS proposed rule and for reasons we set forth previously in this final rule, we are finalizing the proposed revisions to § 414.402 to change the definitions of bid, composite bid, and lead item. We are also finalizing the proposed revisions to § 414.414 and § 414.416 to change the processes for submitting bids, evaluating bids and calculating SPAs based on lead item pricing. However, to eliminate confusion over the inclusion of the words “maximum or highest bid,” in the language of the proposed rule, we are finalizing a slight change to the language in §414.416 to refer to the “maximum bid” submitted for an item rather than the “maximum or highest bid” submitted for an item. We are also making some minor technical changes to § 414.412. In the CY ESRD PPS DMEPOS proposed rule, we incorrectly noted the conforming changes to remaining paragraphs in § 414.412 as a result of the proposal to delete

paragraph (d) of § 414.412, which currently requires suppliers to submit separate bids for each item in the product category. Therefore, along with the removal of paragraph (d), we are finalizing § 414.412 with technical edits to re-designate paragraphs (e) through (h) as paragraphs (d) through (g), respectively. Additionally, in newly redesignated paragraph (e)(2), we are removing the reference to paragraph “(f)(1)” and adding in its place the reference “(e)(1)”; and in newly redesignated paragraph (g)(2)(i)(D) we are removing the reference to “paragraph (h)(3)” and adding in its place the reference “ paragraph (g)(3)”.

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

A. Background

For DME furnished on or after January 1, 2016, section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs. Section 1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in or information is updated as new CBP contracts are awarded. Similarly, sections 1842(s)(3)(B) and 1834(h)(1)(H)(ii) of the Act authorize the Secretary to use payment information from the DMEPOS CBP to adjust the fee schedule amounts for enteral nutrition and OTS orthotics, respectively, furnished in all non-CBAs. Section 1834(a)(1)(G) of the Act requires that in promulgating the methodology used in making these adjustments to the fee schedule amounts, the Secretary consider the costs of items and services in areas in which the adjustments would be applied compared to the payment rates for such items and services in the CBAs.

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

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. We also 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. For further detailed

information, we refer readers to section VI.A.1 of the CY 2019 ESRD PPS DMEPOS proposed rule.

2. Highest Winning Bids in CBAs Analysis

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. We found no pattern indicating that maximum bids are higher for areas with lower volume than they are for areas with higher volume. For further detailed information, we refer readers to section VI.A.2 of the CY 2019 ESRD PPS DMEPOS proposed rule.

3. Travel Distance Analysis

We considered the average travel distances associated with furnishing items and services in CBAs and non-CBAs using two analyses. 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). In non-CBAs, the majority of items that are subject to the fee schedule adjustments are furnished in these two geographic delineations. 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), or core area containing a substantial population nucleus, together with adjacent communities having a higher degree of economic and social integration with that core. We compared the average size of the different areas nationally and by Bureau of Economic Analysis (BEA) region and found that the CBAs have much larger service areas than the non-CBA MSAs and micro areas. Under the CBP, a contract supplier is required to furnish items to any beneficiary in the CBA that requests an item or service from the contract supplier. 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 31, 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. Micro areas are areas where competitive bidding, for the most part, has not yet been implemented, and where the vast majority of items are not competitively bid.

TABLE 31: 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 data in Table 32 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 32 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. This means that the majority of suppliers serving non-CBAs are travelling no further than the distance of the non-CBAs they are located in, which again are much smaller than the CBAs.

TABLE 32: 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%
Non-CBA MSAs	68%	63%	65%
Non-CBA Micro Areas	64%	61%	61%
Non-CBA OCBSAs	78%	82%	81%

In our second analyses, we 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 33 are for hospital beds and oxygen and oxygen equipment, items that are most likely to be delivered locally by suppliers using company vehicles, as well as all items subject to the fee schedule adjustments. We

compared average distances in CBAs versus non-CBAs broken out based on whether the beneficiary resided in an MSA, micro area, or 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). CBAs have greater average service distances than non-CBAs, with the exception of SR areas.

TABLE 33: Average Number of Miles between Supplier and Beneficiary¹

Beneficiary Area	Hospital Beds	Oxygen	All Items
CBAs	25	21	27
Non-CBA MSAs	22	19	24
Non-CBA Micro Areas	23	21	27
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.

The average distances from the supplier to the beneficiary in the CBAs are the same or 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 super rural areas are greater than the average distances for the CBAs. For further detailed information, we refer readers to section VI.A.3 of the CY 2019 ESRD PPS DMEPOS proposed rule.

4. Cost Analysis

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. For further detailed information, we refer readers to section VI.A.4 of the CY 2019 ESRD PPS

DMEPOS proposed rule.

In the CY 2019 ESRD PPS DMEPOS proposed rule, we analyzed the aforesaid cost data, and overall, each cost variable was, for the most part, higher on average in the CBAs than it was for every other geographic delineation (MSA, micro, OCBSA). The more urbanized areas tended to have higher costs than the less urbanized areas. We think this may be due to several reasons.

The Bureau of Labor Statistics explains, "...that the principal differences in overall expenditures between rural and urban households are the amounts spent on the chief elements of housing: mortgage interest and rental payments. These expenditures are affected by many different variables, but can be understood fundamentally by supply and demand, and are often dependent on location. Land is scarce in urban areas, and many people are vying for limited housing; therefore, rent is higher and houses are more expensive. In many rural areas, land is plentiful, so prices tend to be lower."²³

With regard to CBAs generally having higher wages and PE GPCI values, values which attribute much of their calculation to wages, there are several reasons for this as well. A report prepared by RTI International for the Medicare Payment Advisory Commission (MedPac) describes how differences in local labor productivity are partly responsible for the observed differences in nominal wages, which are the wages that appear on paychecks.²⁴ The theory of compensating wage differentials was originally used to explain why nominal wages differ across workers. The report explains how "[t]he term 'compensating' refers to attributes of jobs that attract or repel workers to specific occupations or geographic areas. A job that has repellent

²³ Expenditures of urban and rural households in 2011

<https://www.bls.gov/opub/btn/volume-2/expenditures-of-urban-and-rural-households-in-2011.htm>

²⁴ Geographic Adjustment of Medicare Payments for the Work of Physicians and Other Health Professionals
http://www.medpac.gov/docs/default-source/contractor-reports/jun13_geoadjustment_contractor.pdf?sfvrsn=0

attributes commands a “compensating” amount. Conversely, holding constant other attributes, nominal wages can be lower for jobs that have attractive attributes. The theory of geographic wage differences, then, is the theory of compensating wage differentials applied to the geographic dimensions of wages.”

Additionally, the report describes how geographic variation in wages is affected by the amenities available in different areas. For instance, “[a]menities’ include such factors as climate and local cultural and recreational opportunities. High amenity areas do not need to pay as much to attract workers, hence wages in these areas will be lower relative to their cost-of-living than in areas with low levels of amenities. The reverse is also true; workers may also demand higher real (that is, cost-of-living-adjusted) wages for a job located in an area with unattractive features. The valuation of amenities will differ across individuals, partly related to systematic factors such as education and income, and partly due to idiosyncratic preferences. It may also vary across professions; for example, if physicians value location in an area with access to colleagues and multiple medical facilities, then they might demand a wage premium for locating in isolated rural communities.”

Furthermore, the report mentions that as more workers take jobs in high-wage industries in a given area, they tend to bid up the price of housing, which increases the cost of living and lowers the real wages of workers of other industries in the area.

Lastly, the U.S. Department of Agriculture (USDA) suggests there are several factors that may contribute to higher earnings in urban areas.²⁵ For one, “[b]usinesses that provide skill-intensive employment may be clustered in urban areas, where a larger market allows for closer

25 Urban Areas Offer Higher Earnings for Workers With More Education
<https://www.ers.usda.gov/amber-waves/2017/july/urban-areas-offer-higher-earnings-for-workers-with-more-education/>

proximity to customers and suppliers, shared infrastructure, and better matching between employers and employees. The density of businesses and people in urban areas may also facilitate the promotion and adoption of innovative ideas. These benefits may enhance the productivity of businesses and workers, contributing to higher urban wages.” However, the USDA concludes that other differences between urban and rural workers—such as work experience, job tenure, and ability—may also contribute to higher urban wages. For further detailed information, we refer readers to the CY 2019 ESRD PPS proposed rule (83 FR 34372).

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

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. This is likely due to CBAs generally being located in the most populated areas of the country, with more beneficiaries, and therefore, more suppliers in these areas than in non-CBAs. For further detailed information, we refer readers to section VI.A.5 of the CY 2019 ESRD PPS DMEPOS proposed rule.

6. Number of Suppliers Analysis

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 the number of suppliers in a given area might affect costs, but it does not appear to have been a factor under the competitive bidding program in terms of bids submitted in the various CBAs. For further detailed information, we refer readers to section VI.A.6 of the CY 2019 ESRD PPS DMEPOS proposed rule.

7. Fee Schedule Adjustment Impact Monitoring Data

In an effort to determine whether the fee schedule adjustments have resulted in 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 solicited comments on ways to improve our fee schedule adjustment impact monitoring data (83 FR 34380).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed to base the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently rural or non-contiguous non-CBAs, on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the fee schedule amounts adjusted in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We proposed to pay the fully adjusted fee schedule rates for items and services furnished in non-rural and contiguous non-CBAs from January 1, 2019 through December 31, 2020. We proposed that in the event of a temporary gap in the CBP, we would adjust the fee schedule amounts applicable in each CBA based on the SPA for the area increased by the projected change in the consumer price index for all urban consumers (CPI-U) for the 12-month period ending on the date that the adjusted fee schedule amounts take effect (for example, January 1, 2019). The adjusted fee schedule amounts would be increased every January 1 by a similar update factor for as long as

the temporary gap in the CBP continues. We received approximately 281 public comments on our proposals, including comments from homecare associations, DME manufacturers, suppliers, senior advocacy associations, the Medicare Payment Advisory Commission (MedPAC), Members of Congress, and individuals. Comments related to the paperwork burden are addressed in the “Collection of Information Requirements” section of this final rule. Comments related to the impact analysis are addressed in the “Economic Analyses” section of this final rule.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing.

1. Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas

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 will be in place on January 1, 2019. Thus, we anticipate there will be a gap in the CBP beginning January 1, 2019. During a gap in the CBP beginning January 1, 2019, there will not be any contract suppliers and payment for all items and services previously included under the CBP will 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 proposed 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 have taken into account the information mandated by section 16008 of the Cures Act. 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 collected included 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 beneficiary 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 when adjusting fee schedules in the short term in an effort to 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 final 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 final 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 number of DME supplier locations declined from 13,535 (2015) to 12,617 (2016), indicating 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 audits, investigations, and evaluations by CMS and its contractors that enhanced fraud and abuse controls to monitor suppliers. Furthermore, we have noted in section VI.A.6 of this final 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 unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). 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 because rural and non-contiguous face unique circumstances, such as lower volume, and in certain areas, higher costs. We believe that blended rates can help ensure beneficiary access to needed DME items and services in rural 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 § 414.210(g)(1) through (g)(8). 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 for suppliers in non-rural non-CBAs. We requested specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well (83 FR 34382).

We believe that the changes to the CBP that we outlined in section V “Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)” (which change bidding and the SPA calculation methodology under the CBP for future competitions) 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 proposed 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 from January 1, 2019 through December 31, 2020, based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We proposed 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 § 414.210(g)(1) through (g)(8). 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.

The comments on our proposals and our responses to the comments are set forth below.

Comment: Many commenters supported the proposal to base the fee schedule amounts for items and services furnished in rural and non-contiguous areas during the time period from January 1, 2019 through December 31, 2020 on a 50/50 blend of adjusted and unadjusted rates. Many commenters said that this would help suppliers stay in business and that it would help prevent access issues. Some commenters said rural areas have higher costs than urban areas. For instance, one commenter in Minnesota said that although costs, such as the utility cost and real estate tax data we presented in our CY 2019 ESRD PPS DMEPOS proposed rule, may be higher in urban areas than in some areas of the country, their experience in Minnesota has shown that operating costs for branches in rural areas can be significantly higher than those for urban areas. Another commenter talked about the costs that Native American reservations in very rural areas must face. They include frequent power failures, extreme weather, no running water, lack of cell phone service, and increased travel distances.

Response: We appreciate the support for that proposal.

Comment: Many commenters stated CMS should apply the 50/50 blended rate to items and services furnished in the non-rural non-CBAs. As support for this, commenters stated that 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, and that the decline in number of suppliers has occurred in both rural and non-rural areas, which they claim has resulted in problems obtaining access to items and services and health issues. Some commenters who were suppliers said that they no longer offer some products, and that they do not accept Medicare assignment on several products, and that this non-assignment would increase if the fee schedule amounts for non-rural non-CBAs are not increased. Some

commenters discussed how suppliers in non-rural non-CBAs must travel far distances to deliver DME, and that this and a low population density causes costs to suppliers to be higher in non-rural non-CBAs than in CBAs. One commenter said that when looking at their costs in metropolitan areas, they have a much higher labor cost than rural areas, and the delivery costs are also significant, not because of the distance, but more so because of the downtime with traffic. Another commenter said that there are fewer people in rural non-CBAs than in non-rural non-CBAs, and there are fewer people in non-rural non-CBAs than there are in CBAs. The commenter also said that this serves as a proxy for the volume of patients in the non-rural non-CBAs, and that with fewer patients to spread the costs over, the costs are higher. A few commenters said that in addition to allowing fixed costs to be spread over more patients, there are greater efficiencies of scale available in the CBAs. Therefore, while some costs may increase in CBAs, such as those CMS listed in the CY 2019 ESRD PPS DMEPOS proposed rule, these costs are offset by these economies of scale and the ability of suppliers to spread their fixed costs over multiple patients. Another commenter said that the most significant variables that affect DME supplier costs are labor rates, transportation (fuel, trucks and related costs such as vehicle and driver insurance), population density, miles/time between points of service, and regulatory compliance costs. The commenter stated that the cost of fuel is therefore a significant cost factor, and that in recent years, fuel costs have risen significantly due to the rising cost of petroleum. The commenter then stated that those costs are significantly amplified in non-CBAs where the distances to travel to beneficiaries' homes are much greater.

Response: We agree that 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, and that total population and population density are both lower

in non-rural non-CBAs than in CBAs. However, volume of services furnished is only one factor impacting the cost of furnishing DMEPOS items and services. A number of other factors affecting the costs of furnishing DMEPOS items and services such as wages, gasoline, rent, utilities, travel distance and service area size point to higher costs in CBAs than non-rural non-CBAs. Further, although the cost of fuel may have increased in recent years, as detailed in our CY 2019 ESRD PPS/ DMEPOS proposed rule, the price of gas is overall slightly lower in non-CBAs, and travel distances are generally lower in non-CBAs than they are in CBAs. Travel distances were also only greater in certain non-CBAs, which were Frontier and Remote (FAR), OCBSAs, and Super Rural areas. Additionally, as one commenter pointed out, metropolitan areas generally have higher labor costs than rural areas, and the delivery costs can also be significant because of the downtime with traffic. However, we believe that these factors are likely only amplified in the more heavily populated CBAs.

Also, as discussed in our CY 2019 ESRD PPS DMEPOS proposed rule, past stakeholder input and studies suggest that delivery costs and wages affect a suppliers' overall costs more than equipment acquisition costs and volume discounts (83 FR 34378). 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.²⁶ 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

²⁶ Morrison Informatics, Inc., A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy (Mechanicsburg, Pa.: June 27, 2006).

patients, obtaining required medical necessity documentation, customer service, and operating and overhead costs accounted for 72 percent of overall costs.

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. As we have previously indicated, 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.

We agree that the number of suppliers furnishing items and services subject to the fee schedule adjustments is decreasing in non-rural non-CBAs and we have been monitoring the impact of the fee schedule adjustments in these areas closely. In the non-rural non-CBAs, the percentage of participating suppliers, meaning suppliers who agree to accept Medicare payment for every claim and accept assignment for an entire year, has only slightly decreased in non-CBA non-rural areas from 29.66 percent in January 2015 to 27.73 percent in July 2018, when looking at claims data through week 34 of 2018. It is also worth noting that while volume is lower in the non-rural non-CBAs, and the total number of suppliers has been decreasing steadily since before the implementation of the adjusted fees in 2016, the services per supplier in the non-rural non-CBAs has been increasing during that time. Thus, while volume is generally less in non-rural

non-CBAs than it is in CBAs, the volume per supplier in the non-rural non-CBAs has been increasing. For instance, when looking at data through week 34 of the respective year, from 2016-2017, the services per supplier in non-rural non-CBAs increased by 11.33 percent, and from 2017-2018 it increased by 12.88 percent.

We have not found evidence that this is causing access beneficiary problems or health outcomes issues. Health outcomes for both beneficiaries using items and services subject to the fee schedule adjustments and beneficiaries who may need items and services subject to the fee schedule adjustments have remained stable or have improved since the fully adjusted fees were implemented. Regarding beneficiary access, as shown in Table 34, allowed services for items and services subject to the fee schedule adjustments continue to increase each year and the rate that suppliers are accepting assignment of claims paid at the fully adjusted rates in non-rural non-CBAs remains very high and have increased in 2018 thus far.

TABLE 34: Allowed Services and Assignment Rates for Claims for Items Subject to the Fee Schedule Adjustments Furnished in Non-Rural Non-CBAs

Year	Full Year Data		Claims Paid Through Week 34	
	Allowed Services	Assignment	Allowed Services	Assignment
2015	11,885,241	99.89%	6,288,952	99.89%
2016	12,266,590	99.85%	6,520,165	99.88%
2017	12,484,248	99.81%	6,697,219	99.80%
2018	n/a	n/a	6,954,277	99.83%

As the number of suppliers has decreased in non-rural non-CBAs, the average volume of items and services furnished by suppliers in non-rural non-CBAs has increased, which may explain why the rate of assignment increased slightly in the first half of 2018 in these areas. The high rate of assignment and increase in allowed services indicate that payments in these areas are sufficient to cover the costs of furnishing the items and services in these areas.

Comment: Some commenters said that typically, the same DME suppliers are serving both the non-rural and the remaining non-CBAs, that financial viability and beneficiary access issues are therefore not limited to rural and non-contiguous non-CBAs, and that the blended 50/50 payment rates should thus not be limited to the rural and non-contiguous non-CBAs.

Response: As discussed in our CY 2019 ESRD PPS DMEPOS proposed rule, our data indicates 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 (that is, the percentage of suppliers located in the same area as the beneficiary). For this, we separated the data by CBA, and then non-CBA MSA (non-rural), micro area (rural), or Outside Core Based Statistical Area (OCBSA), which are counties that do not qualify for inclusion in a CBSA (rural). Thus, our data do not confirm that typically, the same DME suppliers are serving both the non-rural and the remaining non-CBAs. In addition, because assignment rates in the non-rural non-CBAs continue to be very high despite the full fee schedule adjustments, we believe the 50/50 blended rates are appropriate for DME items and services furnished in rural and non-contiguous areas, but not in other non-CBAs.

Comment: Some commenters mentioned studies that found beneficiaries had problems obtaining DME. For instance, some commenters mentioned an industry-funded survey done by Dobson DaVanzo & Associates, LLC that claimed that the Medicare competitive bidding program has negatively affected beneficiaries' access to DME services and supplies, adversely impacted case managers' ability to coordinate DME for their patients, and placed additional strain on suppliers to deliver quality products without delay. Some commenters mentioned a survey done by the American Thoracic Society (ATC) that found that supplemental oxygen users experienced frequent and varied problems, particularly a lack of access to effective instruction

and adequate portable systems, and that patients living in Competitive Bidding Program areas reported oxygen problems more often than those who did not.^{27, 28}

Response: The GAO reviewed these and other studies mentioned by commenters that assessed the effect of the implementation of fee schedule adjustments on beneficiaries, DME suppliers, and others in a report titled “Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment” (GAO-18-534). The GAO found that these studies did not provide persuasive evidence of substantial effects of fee schedule adjustments on DME access, primarily because of methodological issues with how the participants in the studies were recruited. Specifically, respondents were recruited on social media platforms or through targeted email notifications, raising concerns about selection bias. The GAO did note that some effects may take longer to appear, underscoring the importance of our continued monitoring activities, and we will continue to monitor the effects of the fee schedule adjustments on beneficiary access to DME items and services.

Comment: A few commenters recommended that CMS develop a mechanism to better understand why utilization has decreased in non-CBAs. Some commenters disagreed with CMS’ determination that a decrease in utilization can be attributed to a reduction in waste, fraud, and abuse.

Response: We would like to note that while utilization of DME varies throughout area and by particular item, the number of total services increased from 2016 to 2017 (2.05 percent), and from 2017 to 2018 (3.08 percent) when looking at the number of total services furnished

²⁷ Dobson DaVanzo & Associates, LLC. Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences. (October 9, 2017).

²⁸ American Thoracic Society. Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy. Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey. (January 1, 2018).

through week 34 of the respective year. There has been a persistent increase in total volume of services furnished in non-CBAs from 2016 to 2018, driven by an increase in CPAP/RADs. All other products exhibit either a continuous decline from 2016 through 2018, or at least a decline from 2017 to 2018. However, when looking at data through week 34 of the respective year, from 2016 to 2017, the services per supplier in non-rural non-CBAs increased by 11.33 percent, and from 2017 to 2018 it increased by 12.88 percent. Rural non-CBAs follow a similar trend, in that when looking at data through week 34 of the respective year, from 2016 to 2017, the services per supplier in rural non-CBAs increased by 10.91 percent, and from 2017 to 2018 it increased by 10.39 percent. Although we cannot be certain how much a decrease in utilization can be attributed to a reduction in waste, fraud, and abuse, the OIG has noted that services provided by DME suppliers have been consistent targets of Medicare fraud schemes, and the OIG has also previously noted that there have been reductions in Medicare billing and payments for certain services and geographic areas known for fraud risks.

Comment: Another commenter said that the geographic areas that CMS examines are too large and heterogeneous to detect access problems or other negative beneficiary outcome issues. The commenter asserted that even the size of the CBAs can be too large to detect access issues related to DMEPOS supplies. The commenter also said that these aggregate data mask important access issues to DMEPOS that may not ultimately result in negative outcomes — but only because hospitals or other stakeholders act to ensure that beneficiaries receive their DMEPOS and related supplies in a timely manner, despite suppliers' failure.

Response: We agree that individual problems with access to items and services may not be detected in the claims and health outcomes monitoring, but we do not agree that widespread issues exist that are undetected. The level of analysis performed would pick up any spikes in the

data if they occurred. For example, an increase in the average length of stay in hospitals and nursing homes that might suggest a delay in receiving DME in the home would be detected and flagged for more detailed analysis. We believe the geographic areas that we examine are appropriate because they allow us to have an appropriately sized study population and that a smaller sized population might prevent us from drawing meaningful conclusions.

Comment: Some commenters, when commenting on ways to improve our fee schedule monitoring data, said that although CMS indicates no significant changes have been observed in assignment rates, nonassigned claims are not an option for dual eligible beneficiaries. This is because all Medicare providers must accept assignment (payment in full) for Part B services furnished to dual eligible beneficiaries. Therefore, the commenters concluded, using assignment rates for people with disabilities and who are eligible for Medicaid is not a valid monitor for access problems.

We also received many comments that focused on furnishing and billing for respiratory services, particularly oxygen. A few commenters said that the assignment rates are an interesting point, but it is not practical to assume that suppliers can seek additional payments from beneficiaries. The commenters said that suppliers take assignment because the beneficiaries cannot afford to pay suppliers directly for the services, and that even a monopoly supplier would take assignment because some payment is better than nothing, especially if there is some hope that policy-makers will reform the system. In addition, the commenters said that due to the rental nature of the equipment, and the compliance rules regarding monthly notification, and acknowledgement of non-assignment to the beneficiary, it is nearly impossible for reputable providers to compliantly bill for respiratory services on a non-assigned basis. Thus, the commenters asserted that assignment data do not really tell policy-makers anything about access.

One commenter said that assignment provides no indication of a supplier's true willingness to accept the Medicare rate for products and services because assignment assumes suppliers can collect the difference in cost from beneficiaries. Another commenter said that any additional charges are highly unlikely to be recouped and will function as bad debt. The commenter also said that unlike other Medicare providers, home respiratory therapy suppliers are not required to report such bad debts and there is no policy to provide any bad debt relief to suppliers. Thus, even if Medicare payment amounts are too low, the commenter said suppliers are unlikely to seek the difference between the rates and the cost of providing equipment and services from beneficiaries, because the cost of seeking the additional payment coupled with the low likelihood of obtaining payment make the process impracticable.

Response: Our data shows that suppliers in the non-rural, non-CBAs accept the fully adjusted fee schedule amounts as payment in full over 99 percent of the time, while allowed services in these areas continues to increase each year. We also would like to note that the assignment rate for suppliers furnishing oxygen in the non-rural non-CBAs was 99.96 percent in 2017, and remains unchanged at 99.96 percent in 2018, when looking at data through week 34 of 2018. Additionally, the number of services per supplier for suppliers furnishing oxygen in the non-rural non-CBAs is also increasing, for example, it increased 2.64 percent from 2016 to 2017, and increased 3.62 percent from 2017 to 2018, when looking at data through week 34 of 2018. We do not believe that a supplier can accept assignment if the payment amount is below their cost, certainly not on a sustained basis over several years. Even when we exclude claims for items and services furnished to beneficiaries dually enrolled in Medicare and Medicaid, which are cases in which suppliers must accept assignment of the claim, the rate of assignment remains extremely high. Table 35 shows the same data from Table 34 for non-rural non-CBAs, after

excluding data for items and services furnished to beneficiaries dually enrolled in Medicare and Medicaid. Thus, the high overall assignment rates in the non-CBAs are not due to cases in which supplier must accept assignment. Rather, high assignment rates are prevalent throughout the non-CBAs. We believe that assignment rates are one effective method of determining whether Medicare payment rates are sufficient, and that these high assignment rates in the non-rural non-CBAs support our decision to apply the fully adjusted payment rates in these areas.

TABLE 35: Allowed Services and Assignment Rates for Claims for Items Subject to the Fee Schedule Adjustments Furnished in Non-Rural Non-CBAs (excluding claims for dual (Medicare/Medicaid)-eligible beneficiaries)

Year	Full Year Data		Claims Paid Through Week 34	
	Allowed Services	Assignment	Allowed Services	Assignment
2015	8,809,268	99.87%	4,639,097	99.87%
2016	9,223,208	99.81%	4,884,326	99.86%
2017	9,487,963	99.77%	5,067,065	99.76%
2018	n/a	n/a	5,374,904	99.79%

Comment: A few commenters recommended that CMS study the number of delivery/service calls a DME provider can make in a day in CBAs and non-CBAs. The commenters stated that the cost per delivery/service call will vary significantly in more densely populated areas than in less populated areas. For example, some commenters stated that in a CBA, a DME supplier can make multiple stops in a day, while a DME supplier in a non-CBA can make significantly fewer. Therefore, the cost per visit in non-CBAs is significantly higher. One commenter went on to explain that this means that DME suppliers in non-CBAs require more trucks, more employees, more fuel (and all the related overhead costs) to be able to serve the same number of beneficiaries. Another commenter disagreed with the way CMS measured its travel distance analysis, saying that CMS operated under the premise that DME suppliers use

single round trips to deliver items to beneficiaries, when DME suppliers rely on the efficiency of routes and volume to deliver items to beneficiaries. The commenter asserted that had CMS started with this presumption of DME operations, they would have arrived at the conclusion that it is more costly to operate in non-CBAs.

Response: Since we do not have data on the number of stops a delivery truck makes and the distance between stops, we are not able to factor this variable into our data for average travel distance. However, our analysis was not based on a premise that DME suppliers use single round trips to deliver items to beneficiaries. We understand that this is not the case in practice and used other data besides the distance between the beneficiary address and the supplier address on claim forms to determine the service areas and delivery distances for suppliers. We looked at the differences in land areas for the CBAs compared to the land areas for non-CBAs (MSAs and micropolitan statistical areas not included in the CBP) and found that the areas served by the contract suppliers under the CBP are much larger than the non-CBA areas. The size of the CBAs are approximately double the size of the MSAs where competitive bidding has not yet been phased in. Data also show that 65 percent of the items furnished to beneficiaries in these MSAs are furnished from suppliers located within the MSA, meaning that the greatest distance the majority of suppliers serving these areas would have to travel to furnish items within these areas is half the distance that suppliers in CBAs would have to travel. We understand that suppliers serving larger, more densely populated areas will generally have more locations, trucks, drivers, and other employees to serve the larger populated areas, but as one commenter pointed out, travel time in heavily populated areas is affected by traffic and costs in larger, more densely populated areas metropolitan areas (wages, rent, utilities, tolls) is higher. Suppliers in CBAs will spend more money on rent and utilities, trucks, and wages to serve the larger, more densely

populated urban areas than suppliers in smaller, less densely populated non-CBA urban areas. So, even though the supplier in the larger, more densely populated area may have more items to spread these costs over, the costs they spread over the items are considerably greater. We have not found that the total costs of suppliers in non-rural, non-CBAs are greater than or less than the total costs of suppliers in CBAs, nor have we seen data suggesting that the cost per visit in non-CBAs is significantly higher than in CBAs.

Comment: A few commenters stated that CMS should have compared the average travel distance and cost, the average volume of items and services furnished by suppliers, and the number of suppliers in CBAs to the average travel distance and cost, the average volume of items and services furnished by suppliers, and the number of suppliers in all non-CBAs, and not by any other geographic delineation (MSAs, micropolitan statistical areas, super rural areas, etc.). The commenter stated that the Cures Act mandated the Secretary to take into account a comparison of certain factors with “respect to non-competitive acquisition areas and competitive acquisition areas” when determining fee schedule adjustments for items and services furnished after January 1, 2019. The commenter also stated that as a result, CMS should make the same fee schedule adjustments for all non-CBAs, regardless of whether the area is rural or non-rural. Some commenters stated that because Congress passed Section 16007 of the Cures Act, which retroactively applied the 50/50 blended rates in all non-CBAs from June 30, 2016 to December 31, 2016, that it was the intent of Congress in passing section 16008 of the Cures Act for CMS to increase payment in all non-CBAs.

Response: We took into consideration the issues that stakeholders have raised for this analysis. Many stakeholders have claimed that the costs of furnishing items and services in rural areas are different than the cost of furnishing items and services in urban areas. Specifically,

stakeholders have indicated that costs in rural areas are higher than costs in urban areas. All CBAs are currently located in MSAs or urban areas, whereas non-CBAs are a mixture of areas that are urban/MSAs (similar to CBAs) and other areas that are rural (not similar to CBAs). Based on stakeholder input, it is important to distinguish between urban and rural areas, and separately analyzing data for rural and urban non-CBAs and comparing this data and information to data and information for CBAs comports with this stakeholder input. Section 16008 of the Cures Act mandated that CMS take certain information into account when adjusting fee schedule amounts for items furnished on or after January 1, 2019. Section 16008 of the Cures Act does not require CMS to adjust fee schedule amounts any differently (upward or downward) based on this information. CMS conducted an analysis of the factors outlined in section 16008 of the Cures Act, and the results of the analysis are summarized in this final rule and in the proposed rule (83 FR 34380). Based on the stakeholder comments, and our data showing 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 unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8).

Comment: Some commenters recommended that CMS adopt add-on payment policies for the non-CBAs. For instance, a few commenters recommended that after the end of the blended rate extension, that CMS establish two percentage add-ons for the non-CBA areas: one

for the non-rural non-CBAs and one for the rural non-CBAs. The commenters recommended setting the non-rural non-CBAs at the regional SPA + 16 percent, and the rural non-CBAs at the regional SPA + 22 percent. The commenters said that these amounts are based on data obtained from a survey of suppliers indicating that costs were 5 percent higher than the SPAs in CBAs and the cost differential they identified through their cost survey. As an example, a few commenters mentioned that Congress set the ambulance fee schedule urban and rural add-ons through statute, but left the calculation of the super rural add-on to CMS to determine. To make this calculation, CMS used existing GAO report data that ultimately supported the current super-rural add-on of 22.6 percent. One commenter said that this supports paying higher in these super-rural areas. Another commenter said that once CMS implements the next CBP, CMS should apply rural and super-rural add-on payments to all non-CBAs.

One commenter recommended that CMS establish a special payment policy for suppliers providing service to rural beneficiaries. The commenter mentioned how, currently, CMS uses a special rule for rural areas for items included in more than 10 CBAs. In addition, the commenter said CMS could supplement this special rule by making it more generous, and also applying the national ceiling prices in areas with a limited number of suppliers or low average volume of Medicare business. As an example, the commenter said the national ceiling amount could apply to areas with low volume of Medicare business or to suppliers meeting a low numerical threshold; for instance, the lowest quartile based on volume of a particular DMEPOS item or number of suppliers in an area. The commenter also said that this would help boost payment levels in other markets, and not just rural ones. In addition, the commenter also suggested CMS as another option, or in addition to the aforesaid policy, establish an add-on payment for these defined low volume or low supplier areas, based on its general approach used for rural areas in

the ambulance fee schedule. The commenter also said that this could involve increasing the base payment by a percentage amount such as 10 percent.

One commenter recommended CMS conduct its own survey of costs to support the cost differential. The commenter also recommended that CMS extend the blended 50/50 payment rates in rural and non-rural non-CBAs until CMS can determine and implement the appropriate percentage add-on adjustments. Another commenter welcomed the opportunity to work with CMS to identify the specific data such a survey would collect and to work with other stakeholders.

One commenter recommended that CMS should add another percentage add-on to the current 50/50 blended rates in rural areas.

Another commenter said that CMS should create a formula to factor in costs due to distance and a lack of other patients. Similarly, another commenter said CMS should ensure there are a sufficient number of qualified suppliers within certain distances of rural and non-contiguous service areas to ensure products are available within acceptable time frames.

Response: We thank the commenters for their specific recommendations regarding adopting add-on payments for items and services furnished in non-CBAs. We did not propose any payments like those described by commenters. We will keep these recommendations in mind for future rulemaking.

We currently believe that finalizing the fee schedule adjustment policy of paying the 50/50 blended rates for items and services furnished in all rural and non-contiguous non-CBAs ensures access to DME in all of these areas and is administratively simpler than applying payments like those described by commenters only in certain areas. We recognize that there are certain supplier cost and volume differences in rural and non-contiguous non-CBAs, which is

why this final rule distinguishes rural and non-contiguous non-CBAs from other non-CBAs and results in higher payments to suppliers furnishing items in the rural and non-contiguous non-CBAs. We also believe that paying an amount in addition to the blended 50/50 payment rates would be excessive and unnecessary, and not in line with what most commenters requested, as most commenters specifically requested the blended 50/50 payment rates in rural and non-contiguous non-CBAs. This indicates that such payment rates are sufficient, which is why we are also not incorporating the ambulance fee schedule's concept of a super rural add-on into our payment. We do not believe that we need to conduct a survey of costs, as we have already analyzed several cost data variables as part of section 16008 of the Cures Act, as discussed in section VI.A.4 of the CY 2019 ESRD PPS DMEPOS proposed rule, and briefly described in section VI.A.1 in this final rule.

We will continue to monitor the effects of these adjustments. However, as discussed in section VI.A.7 of the CY 2019 ESRD PPS DMEPOS proposed rule, we have been monitoring the effects of the fee schedule adjustments since they took effect in 2016 in non-CBAs, and the data 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.

Comment: A few commenters commented on our analysis of maximum winning bids for section 16008 of the Cures Act. One commenter said that CMS did not include in its analysis the

bidding logic used by those who submitted bids, and the commenter went on to say that the factors that play a role in how one determines their bid amount are bid ceilings, median pricing, potential increased volumes, limited competition, out of area bid winners, how much of the service area is impacted by a bid area and the ability to remain in the Medicare business or not, logic, emotion, and financial impact. A few commenters said that they were not surprised that we found no discernable patterns in the maximum winning bids, given that, as the commenter says, the ability of suppliers to game the current methodology, a lack of transparency, and confusion around the bid ceiling, and that it is unlikely that the bids represent a true gauge of cost or reflect rationale and consistent behavior. The commenters went on to say that they believe that if the proposed changes to the CBP in section V of the CY 2019 ESRD PPS DMEPOS proposed rule are finalized, there will be more rational behavior among suppliers when determining their bids, which will lead suppliers to bid in a way that is more reflective of their costs and the markets they are serving.

Response: We agree that many factors influence what amount a supplier will submit as their bid amount, but there is no way to itemize all of the possible factors and which factors are more important to which types of suppliers. The circumstances surrounding the costs and efficiencies of every individual supplier as well as the bidding strategies they use can vary widely from supplier to supplier. We believe this reinforces the fact that this factor (the highest winning bid in an area is subjective and supplier-specific) provides little to no insight regarding supplier costs in general and how fee schedule amounts should be adjusted in non-CBAs.

Comment: A few commenters raised concerns with our proposal to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-CBAs from January 1, 2019 through December 31, 2020 based on a blend of 50 percent of the unadjusted fee

schedule amounts and 50 percent of the adjusted fee schedule amounts. The Medicare Payment Advisory Commission (MedPAC) did not support our proposal to pay the 50/50 blended rates for items and services furnished in rural and non-contiguous areas and said CMS should adopt a more limited, targeted, and less costly approach. MedPAC said that using 50/50 blended payment rates results in large payment increases, often of 50 percent or more. MedPAC also said that while CMS presents data indicating that some supplier costs are higher in rural and non-contiguous areas, the agency also found that other costs are lower in those areas, and the agency does not present data to justify the large magnitude of the proposed adjustment. MedPAC also said that the 50/50 blended payment rates in all rural and non-contiguous areas for all DMEPOS products included in the CBP is not well targeted. For example, MedPAC noted that micropolitan areas (which are considered rural for the purposes of fee schedule adjustments) likely face different challenges than remote, non-contiguous areas. Finally, MedPAC as well as another commenter, noted that the 50/50 blend rates creates a financial burden for the Medicare program and beneficiaries. Commenters noted that over 2 years, we estimate that the proposed fee schedule adjustments will cost more than \$1.3 billion dollars—\$1.05 billion for the Medicare program and \$260 million in beneficiary cost sharing. MedPAC also noted the \$360 million in additional costs incurred by the Medicare program and beneficiaries associated with using 50/50 blended rates in rural and non-contiguous areas for the last seven months of 2018, as a result of the interim final rule published in the **Federal Register** on May 11, 2018, titled “Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas” (83 FR 21912). MedPAC said that it continues to believe that CMS should use its current statutory authority (and seek additional legislative authority where necessary) to expand the CBP to offset

these increased burdens. MedPAC said that expanding the CBP into new product categories, such as orthotics, would produce substantial savings and help prevent fraud and abuse.

Response: We thank the commenter for raising their concerns with us regarding our proposal to pay the 50/50 blended rates for items and services furnished in rural and non-contiguous non-CBAs. The extension of these blended rates is for a 2-year period and we will continue to monitor the effects of these rates. Based on the stakeholder comments, our data showing 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 unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210 (g)(1) through (g)(8).

Comment: MedPAC supported the proposal to continue to fully adjust the fee schedule amounts for items and services furnished in non-rural, contiguous non-CBAs based on information from the CBP. MedPAC believes CMS's analyses, which suggest that the travel distance and costs are lower in non-rural non-CBAs relative to CBAs, support fully adjusting the fee schedule amounts based on information from the CBP, instead of using a 50/50 blend of adjusted and unadjusted fee schedule amounts. In the long term, MedPAC said that CMS should use its current authority to expand the CBP to non-rural, non-CBAs to the extent any future concerns arise about the appropriateness of using CBP rates from large non-rural areas to set payment rates in smaller non-rural areas.

Response: We thank MedPAC for their support of our proposal with respect to the fee schedule adjustments for items and services furnished in non-rural, contiguous non-CBAs. We agree that our analyses, which suggest that the travel distance and costs are lower in urban non-CBAs relative to CBAs, and support fully adjusting the fee schedule amounts for items and services furnished in non-rural, contiguous non-CBAs based on information from the CBP instead of using a 50/50 blend in such areas.

Comment: In the 2019 ESRD PPS DMEPOS proposed rule, we sought comments on ways to improve the fee schedule monitoring data that we use to monitor beneficiary health and access issues in the non-CBAs. These comments were outside the scope of the proposals. A few commenters suggested creating a position within CMS, such as an ombudsman, whose position would be to monitor and address access, quality, supplier availability, and other issues regarding the adequacy of payment levels in non-CBAs. One commenter said that because CMS already has an ombudsman focused on CBAs, an ombudsman focused on non-CBA issues would be able to better understand the impacts of payment rates in non-CBAs.

Some commenters said that it is impossible to track changes in the features and options available to Medicare beneficiaries within the CBP compared to those available to beneficiaries outside of the CBA due to the fact that the HCPCS codes contain heterogeneous products. The commenters recommended that CMS enable better monitoring of changes in product offerings as a result of the CBP and fee schedule adjustments through HCPCS coding. One commenter said that CMS has no measure of the access to services or the quality of services provided.

One commenter recommended that CMS examine the 2013 fee-for-service diabetic population that used insulin at the time, and track that population through 2017, with cohorts for those continuing use of diabetic testing supplies compared to those not using or discontinuing

their use of diabetic testing supplies, and to assess the outcomes and costs for Part A and B for each subgroup by year.

A few commenters recommended that CMS compare the number of Medicare beneficiaries with chronic obstructive pulmonary disease (COPD) with the number of beneficiaries receiving home oxygen therapy. One commenter requested a standard benchmark to assess whether the percentage of patients who require the therapy because of their diagnosis actually receive it.

Another commenter said CMS should determine whether hospital data, admissions, or readmissions are specific enough to track admissions/readmissions related to complications associated with noncompliance with home respiratory therapy. The commenter also noted that the analysis should be sensitive to whether metrics of hospitalizations for other chronic conditions are improving but the metric for COPD patients is flat or declining, which could indicate that there is a problem with access to home therapies.

A few commenters said CMS should determine whether SNF/long-term care (LTC) beneficiaries using home respiratory therapies is increasing, and that an increase might suggest that patients are being institutionalized rather than being able to remain in their homes.

Other commenters said CMS should survey prescribers of home respiratory therapy to evaluate the difficulty of discharging patients who require such therapy.

Some commenters recommended that CMS support the ATC survey of patients and suggest modifications to target questions about services more specifically.

More commenters said CMS should enhance beneficiary awareness of the CMS complaint process and publicly report on the complaints it registers, and not just those that are ultimately resolved by a supplier.

They also said CMS should establish a patient satisfaction survey/patient-reported outcomes measure for home respiratory therapy that would capture issues like isolation, reduced services, reduced delivery areas, and other impacts that cannot be measured using claims data.

One commenter agreed that hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, and emergency room visits are all reasonable indicators for continued monitoring. The commenter encouraged CMS to also consider obtaining and monitoring information from discharge planners, prescribers and beneficiaries regarding delays and issues in obtaining DMEPOS services for their patients in impacted areas.

Another commenter said that the approach CMS currently uses to monitor access solely through review of claims data would not capture these, or similar, situations. In addition, the commenter then recommended a more refined and granular approach to detect meaningful differences that CMS can act on as part of an ongoing monitoring approach. The commenter also believed that a quantitative approach complemented by a qualitative approach, such as ongoing surveys or selective case studies of sites where issues have been reported, would improve CMS' efforts to monitor beneficiary access and health outcomes and provide more actionable data to resolve access-related issues.

Response: We thank the commenters for suggesting ways in which to improve our fee schedule monitoring data. We will take these comments into consideration going forward.

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 recomplete contracts under the program before the DMEPOS competitive bidding contract periods of performance end, we proposed 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 payment amounts that are comparable to the SPAs 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 proposed 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 proposed 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 proposed 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 proposed to revise § 414.210(g)(4), so that it does not conflict with the proposed new paragraph (g)(10), by revising the first sentence in paragraph (g)(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 SPAs from competitive bidding programs that are no longer in effect, the SPAs 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 requested comments on these proposals.

The comments and our responses to the comments on our proposals for fee schedule adjustments for items and services furnished in former CBAs during a gap in the DMEPOS CBP are set forth below.

Comment: Several commenters endorsed increasing the payment levels in former CBAs beyond the proposal to adjust the fee schedule amounts in former CBAs based on the SPA increased by the projected percentage change in the CPI-U for the 12 month period ending January 2019. Some commenters raised a concern that the SPAs were based upon bids from suppliers who anticipated a larger volume of business as contract suppliers than what would occur starting January 1, 2019, in the former CBAs when any supplier can furnish the items and services. Some DME suppliers and industry associations said that without that greater volume,

prices will have to increase to better ensure continuing beneficiary access. Other commenters stated that during the gap period in competitive bidding, CMS should recalculate SPAs based on the clearing price (maximum winning bids) and change the reimbursement rates for the non-CBAs and CBAs accordingly until the next round of competitive bidding begins. Some commenters recommended that CMS should apply the 50/50 blended rates to the former CBAs, until the next round of competitive bidding takes place. Other commenters recommended that CMS adjust the SPAs in the former CBAs by adding a CPI-U increase compounded from 2013 through 2018 or 2019 to generate the adjusted 2019 CBA SPA rate, as 2013 was when the CBP was expanded throughout the nation under Round 2. Another commenter said that previously contracted suppliers should not be penalized for providing service in CBAs during the contract terms, and that CMS should pay a premium to previously contracted suppliers to offset the reduction in the volume of patients, such as 15 percent.

Response: We thank the commenters for their recommendations for how to adjust the fee schedule amounts for items and services furnished in the former CBAs during the gap in the CBP. We believe that the CY 2019 ESRD PPS DMEPOS proposed rule, which we are finalizing, will result in adequate fee schedule amounts given that the SPAs that the adjusted fees are based on are the same amounts that have been used to adjust the fee schedule amounts for non-rural non-CBAs since January 1, 2017, and suppliers in these areas have accepted these rates as payment in full over 99 percent of the time. Stakeholders overwhelmingly have claimed that costs in non-rural non-CBAs are higher than costs in CBAs based on differences in population and volumes of items furnished. Thus, if fully adjusted fees based on SPAs are sufficient to cover the costs in the non-rural, non-CBAs, they should be sufficient to cover the costs in the higher populated, higher volume areas. As shown in Table 50 of the CY 2019 ESRD PPS

DMEPOS proposed rule (83 FR 34377), for items subject to the fee schedule adjustments, the 2016 allowed services in CBAs are approximately double the 2016 allowed services in non-rural, non-CBAs.

We believe that adjusting fees based on maximum winning bids would result in excessive payments based on this same logic.

Comment: Some commenters opposed the proposed rule, and specifically focused on the payment amounts for mail order diabetic supplies, requesting higher payments. They cited previous payment reductions for suppliers, a decline in the number of suppliers, claims that there are lower quality supplies due to the National Mail Order CBP, potential health and access issues during the gap in the National Mail Order, and the National Mail Order CBP contract periods of performance ending on December 31, 2018 as reasons why payments should be higher for mail order diabetic supplies during the gap in the CBP. Lastly, multiple commenters suggested ways CMS should pay higher amounts for diabetic testing supplies during the gap in the National Mail Order CBP. A few commenters said CMS should return to the unadjusted fee schedule reimbursement rate, or the lesser of the supplier's charge for an item. A few other commenters recommended that CMS apply an inherent reasonableness standard based on valid and reliable data, and reduce the unadjusted fee schedule price of a box of diabetic test strips by fifteen percent, for instance. A few commenters said that there was an average 45 percent reduction in the SPA for items in product categories other than diabetic testing supplies, and as a result, CMS should apply a 45 percent reduction in the price of diabetic testing supplies from the unadjusted fee schedule amount, which would result in a SPA of \$18.70 per box. One commenter went on to say that if CMS decides to maintain the current reimbursement structure of SPA plus CPI-U for all former CBAs, CMS should set the SPA for diabetic testing supplies at the \$18.70 amount

plus the CPI-U for every 12 months since 2013, or set an amount that is above \$20 per box for blood glucose test strips.

Response: We thank the commenters for their recommendations for how to adjust the fee schedule amounts used to pay for mail order diabetic testing supplies during the gap in the National Mail Order CBP. We believe that the proposed fee schedule adjustment methodology will result in payment amounts that will be adequate given the high rate of assignment of claims by suppliers for non-mail order diabetic testing supplies since July 2016, when fee schedule amounts adjusted based on the current SPAs from the National Mail Order CBP were implemented. We will continue our monitoring efforts during the gap in the CBP once contracts expire. With regard to the comment recommending that CMS apply an inherent reasonableness standard based on valid and reliable data in establishing the fee schedule amounts for mail order diabetic testing supplies during the gap in the CBP, we note that the 15 percent threshold the commenters refer to is used to determine which of two processes outlined in section 1842(b)(8) of the Act CMS must follow when invoking the inherent reasonableness authority to adjust fee schedule amounts for items and services not subject to competitive bidding. This threshold has little bearing on what a reasonable payment amount is for diabetic testing supplies.

Comment: A few commenters said CMS did not have the authority to adjust fee schedule amounts for diabetic testing supplies by the current SPAs. For instance, one commenter stated section 1834(a)(1)(F)(ii) of the Act does not provide authority for fee schedule adjustments during a gap in the CBP because the commenter believed section 1834(a)(1)(F) only applies where there is an active CBP. The commenter went on to say that CMS did not follow the process required by section 1834(a)(1)(G), as amended by section 16008 of Cures Act, which as discussed in section VI of this final rule, requires that the Secretary 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, 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.

The commenter also said that section 1834(a)(1)(B) of the Act requires that, in the absence of a CBP, the Secretary make payments based on the unadjusted fee schedule, and that according to section 1834(a)(1)(F) of the Act, in these situations, the Congress established a reimbursement scheme for DMEPOS centered around a default payment of the lesser of the actual charge or the unadjusted fee schedule. The commenter asserted that reimbursing items based on the SPA is an exception to this more general rule and is only done for items and services included in, as section 1834(a)(1)(F) of the Act says, a “competitive acquisition program in a competitive acquisition area.” The commenter said that since there will be no competitive acquisition program for diabetic testing supplies beginning on January 1, 2019, this special rule does not apply, and the payment must be based on the unadjusted fee schedule.

The commenter also discussed how CMS has taken this approach on at least two occasions. The first being during a previous gap in the CBP, in which CMS paid for diabetic testing supplies based on the fee schedule, and contracts for bidding on mail order diabetic testing supplies were in place from January 1, 2011 through December 31, 2012, and then again from July 1, 2013 through June 30, 2016. For that gap period of January 1, 2013 to July 1, 2013,

the commenter said that CMS paid based on the fee schedule rates across all regions.

The other occasion the commenter discussed was when CMS resorted to the fee schedule during the first round of competitive bidding when an auction was considered “nonviable” because beneficiary demand could not be met by qualified suppliers. In the seven Round 1 auctions that were considered nonviable, the commenter said that the DME items in that competitive bidding area were paid according to the “fee schedule and all Medicare enrolled DME suppliers [were allowed to] continue . . . to submit DME claims for these items in that [competitive bidding area].”

The commenter also stated that if CMS determines that the payment amounts based on the fee schedule are not inherently reasonable, CMS can use its authority under section 1842(b)(8)(A)(i) of the Act to adjust the amounts. Under this section, the commenter said that CMS has the ability to deviate from the fee schedule and alter payment rates for items or services that are “grossly excessive or grossly deficient” and to determine an amount that is “realistic and equitable.” The commenter concluded by saying that it is this authority and not the authority in section 1834(a)(1)(F) of the Act that would allow CMS to adjust the fee schedule for diabetic testing supplies.

Response: We disagree with the commenters’ assertions that we do not have the authority to adjust fee schedule amounts for mail order diabetic testing supplies furnished beginning January 1, 2019 by the current SPAs. In the Patient Protection and Affordable Care Act (the Affordable Care Act), Congress mandated fee schedule adjustments for items and services furnished in non-CBAs using the payment determined under the CBP. The relevant section of the Affordable Care Act (section 6410(b)) is titled “Requirement to Either Competitively Bid Areas or Use Competitive Bid Prices by 2016.” The intent of the CBP and

fee schedule adjustments is to thus pay SPAs in CBAs and generate savings in other areas, either by bidding or by adjusting fee schedule amounts based on the payment determined under the CBP. In addition, in the final rule 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” (79 FR 66120), we finalized § 414.210(g)(4), which describes fee schedule adjustments when the only information available is from a competitive bidding program no longer in effect. Thus, CMS has already promulgated a rule to address instances when items are no longer competitively bid. Consistent with that policy, we believe we should continue to adjust the fee schedule amounts for such items during a gap in competitive bidding rather than reverting to completely unadjusted fee schedules. We note that when promulgating this rule, we did take into account the relevant factors under section 16008 of the Cures Act for items furnished in former CBAs, including mail order diabetic testing supplies. With regard to mail order diabetic testing supplies, average travel distance is not applicable since these items are mail order items. Shipping and handling charges typically do not change based on the distance the item is mailed or shipped. The number of mail order suppliers during the gap should be higher and the average volume of mail order diabetic testing supplies furnished by suppliers during the gap will be somewhat lower than the average volume of mail order diabetic testing supplies furnished by suppliers under the CBP. We do not believe that this will have a significant impact on the overall cost of the diabetic testing supplies or the ability of the suppliers to furnish the items at approximately the same rate as suppliers of non-mail order diabetic testing supplies.

Lastly, we disagree with the commenter that the requirement to adjust fee schedule amounts does not apply if there is not an active CBP in place for an item, and that CMS should

instead invoke its authority under section 1842(b)(8)(A)(i) of the Act to adjust the fee schedule amounts for diabetic testing supplies. Under section 1834(a)(1)(F) of the Act, if items furnished on or after January 1, 2011 are included in a CBP, the fee schedule amounts must be adjusted for those items if they are furnished on or after January 1, 2016 outside of CBAs. Diabetic testing supplies have been included in the national mail order CBP from January 1, 2011 through December 31, 2018, and because the statute mandates the adjustment of the fee schedule amounts based on the payment determined under the CBP for items furnished on or after January 1, 2016, CMS must continue to adjust the fee schedule amounts for such items furnished on or after January 1, 2019.

Final Rule Action: After consideration of comments received on the proposed rule and for reasons we set forth previously in this final rule and in the proposed rule, we are finalizing the three fee schedule adjustment methodologies we proposed without change. Specifically, we are finalizing the proposed revisions to § 414.210(g)(9) to adjust the fee schedule amounts for items and services furnished in rural and noncontiguous non-CBAs by extending through December 31, 2020 the current fee schedule adjustment methodology which bases the fee schedule amounts on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts. We are also finalizing our proposal to continue fully adjusting the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in non-rural and contiguous non-CBAs in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We are also finalizing the proposed addition of paragraph (g)(10) to § 414.210 to establish a methodology for adjusting fee schedule amounts for items and services furnished in former CBAs during temporary gaps in the DMEPOS CBP.

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 addresses 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) (Pub. Law No. 109-171), 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 2007 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 paying 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 while portable gaseous or liquid oxygen equipment 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 CMS 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. 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 OGPE. Stakeholders have suggested that the budget neutrality requirement should not 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. We disagree. As long as the add-on payment amounts for OGPE are higher than the add-on payment amounts that would otherwise have been made if the OGPE class not been established, an offset is required to ensure budget neutrality.

As of January 1, 2018, the average adjusted monthly fee schedule add-on amount was \$40.08 for OGPE and \$18.20 for portable gaseous and liquid oxygen equipment. 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 if the OGPE class not been established, 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 class had not been established.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

We received approximately 65 oxygen-related public comments on our proposals in the CY 2019 ESRD PPS proposed rule, including comments from suppliers and industry representative groups.

In this final rule, we provide a summary of the proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing.

1. Adding a Portable Liquid Oxygen Equipment Class and a Liquid High-Flow Oxygen Contents Class and Applying Budget Neutrality Offset to All Oxygen and Oxygen Equipment Classes

We proposed in the CY 2019 ESRD PPS proposed rule (83 FR 34383 through 34386) to revise § 414.226(e) 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 proposed splitting this class into two classes and increasing the add-on amount for portable liquid oxygen equipment. We proposed 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. 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

In § 414.226(e) we also proposed to add a separate payment class for portable liquid oxygen contents for prescribed flow rates of more than 4 liters per minute. We proposed 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. For patients with high flow needs who are also ambulatory, the liquid portable oxygen modality is the only one that allows use of the contents for more than a short period of time. We believe that adding this class and higher payment would encourage suppliers to furnish this modality when it is requested by beneficiaries. Table 36 compares the current classes of oxygen and oxygen equipment and the proposed classes of oxygen and oxygen equipment.

TABLE 36: Current and Proposed Oxygen and Oxygen Equipment Classes

Current Oxygen and Oxygen Equipment: 5 Classes Described in 414.226	Proposed Oxygen and Oxygen Equipment, for years after 2018: 7 Classes Described in 414.226
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

We proposed to change § 414.226(c)(6) and the methodology for applying the budget neutrality offset in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34385 through 34386), in addition to adding the two new proposed oxygen and oxygen equipment classes. We proposed to apply the budget neutrality offset to all items of oxygen and oxygen equipment, rather than just stationary oxygen equipment. This proposed approach would lower the amount of the offset applied to stationary equipment. Table 37 is an example of the 2018 fee schedule amounts when the budget neutrality offset is applied only to the stationary oxygen equipment rate versus the proposed approach of 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 United States.

TABLE 37: 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		\$34.73
		Oxygen generating portable equipment only	
Stationary oxygen contents only	\$53.32	Stationary oxygen contents only	\$49.46
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

For further detailed information, we refer readers to section VII.B of the CY 2019 ESRD PPS DMEPOS proposed rule.

We solicited comments on these proposals.

Comment: Some commenters simply stated that the payments for portable liquid oxygen equipment and high-flow liquid contents are too low given the high cost of furnishing these items.

Response: We agree that the cost of furnishing liquid oxygen and oxygen equipment is higher than the cost of furnishing other oxygen modalities. The proposals, which we are finalizing, will increase payment for portable liquid oxygen and oxygen equipment and portable oxygen contents for patients with high flow needs and therefore, will help to address the higher costs of these modalities. Although we could increase the rates by more than the amount we proposed, any increase to payment amounts would require a higher budget neutrality off-set. We believe the best course of action is to see what effect finalizing the proposed changes will have on access to liquid oxygen and oxygen equipment before deciding to increase the rates further and requiring a larger off-set to be applied to other items.

Comment: One commenter representing Medicare beneficiaries supported the proposed rule for establishing separate classes and higher payments for portable liquid oxygen equipment and high-flow liquid oxygen contents because of the unique nature of furnishing liquid oxygen and its higher cost.

Response: We agree and appreciate the support for the proposed provisions. For this and the reasons we set forth previously, we are finalizing the separate classes and higher payments for portable liquid oxygen equipment and high-flow liquid oxygen contents.

Comment: Many commenters stated that the budget neutrality adjustment should not apply to fee schedule amounts adjusted based on information on the payment determined under the CBP because they believe that the budget neutrality requirement no longer applies once fee schedule amounts have been adjusted based on information from the CBP.

Response: We do not agree. Section 1834(a)(1)(F)(ii) and (iii) of the Act mandates that the fee schedule amounts for DME be adjusted using information on the payment determined under the CBP and does not set aside the requirement of section 1834(a)(9)(D)(ii) of the Act. Section 1834(a)(9)(D)(ii) of the Act specifies that separate classes of oxygen and oxygen equipment may only be created to the extent that they do not result in expenditures for any year that are more or less than the expenditures which would have been made if such classes were not created. Even though the fee schedule amounts for oxygen and oxygen equipment have been reduced using information on the payment determined under the CBP, without a budget neutrality off-set, current expenditures for oxygen and oxygen equipment would be more than the expenditures which would have been made if the OGPE class was not created. Therefore, in order to ensure that expenditures are not more or less than they would have been without the introduction of higher payment oxygen classes, we must apply a budget neutrality off-set to the

classes of oxygen and oxygen equipment even if we have already adjusted the fee schedules based on information from the CBP.

Comment: One commenter recommended spreading the budget neutrality offset over all items of DME rather than the proposed rule to spread the offset over all items of oxygen and oxygen equipment.

Response: We do not believe that payments should be reduced for DME items other than oxygen and oxygen equipment, since many suppliers who furnish such other items do not furnish oxygen and oxygen equipment and therefore are very unlikely to benefit from the higher payments resulting from the additional, separate classes of oxygen and oxygen equipment.

Final Rule Action: After consideration of comments and for reasons we set forth previously in this final rule and in the CY 2019 ESRD PPS DMEPOS proposed rule, we are finalizing the proposals as proposed. Specifically, we are finalizing the proposed revisions to § 414.226(e) to establish the following classes of items: portable gaseous equipment only; portable liquid equipment only; portable oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute; and portable liquid oxygen contents for prescribed flow rates greater than four liters per minute. We are also finalizing the proposed revision to § 414.226(e) to initially set the monthly payment rate for portable liquid equipment only, based on the monthly payment rate for OGPE and to subsequently adjust the monthly payment rates using the applicable methodologies in § 414.210(g) for items and services furnished beginning January 1, 2019. We are also finalizing the proposed revision to § 414.226(e) to initially set the monthly payment rate for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute based on 150 percent of the monthly payment rate for portable oxygen contents only, and to subsequently adjust the monthly payment

rates using the applicable methodologies in § 414.210(g) for items and services furnished beginning January 1, 2019. We are finalizing the proposed revisions to § 414.226(e) to make annual adjustments beginning in 2019 to the monthly payment rates for all items of oxygen and oxygen equipment in order to ensure the annual budget neutrality of all classes of oxygen and oxygen equipment. Further, we are finalizing the proposed revision to § 414.226(f) to explain the application of the monthly fee schedule amounts as listed in § 414.226(e). As proposed, we are to re-designating paragraphs § 414.226(e), (f) and (g) to § 414.226(g), (h), and (i), respectively. We are also finalizing a number of changes throughout § 414.226 and in § 414.230(h) due to the redesignation of paragraphs (e), (f) and (g) of § 414.226. For example, as proposed, we are finalizing a technical edit to § 414.230(h) – we are by removing the reference to “§ 414.226(f)” and adding in its place a reference to “§ 414.226(h)”. In newly redesignated paragraph (g)(1)(i), we are removing the reference to “paragraph (e)(2)” and replacing it with “paragraph (g)(2)”; and in newly redesignated paragraph (g)(2)(ii) by removing the reference “paragraph (e)(2)(i)” and adding in its place the reference “paragraph (g)(2)(i).”

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. Significantly, the payment rules for these categories are different and in some cases mutually exclusive. Table 38 provides a general summary of the payment categories, corresponding payment methodology, and statutory

and regulatory provisions. 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). There are some differences in the payment rules for the payment categories. For example, while sections 1834(a) (2), (4), (6), and (7) of the Act allow for the lump sum purchase of certain items classified under these categories, 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 in 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 (capped rental items).

TABLE 38: Summary of DME Equipment Payment Categories and Rules¹

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.

¹ This is a general summary of the DME payment rules. The reader should refer to the statute and regulations for the full payment rules.

The Medicare allowed amount for DMEPOS items and services paid under the DMEPOS fee schedule in accordance with section 1834 of the Act (outside of the CBP) 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.

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 category in section 1834(a)(5) of the Act, and the functions of a nebulizer, a suction pump, and a cough stimulator classified under section 1834(a)(7) of the Act. In particular, 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 39, 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 denote 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 39: Functions, Payment Category, and HCPCS Codes for DME Items that Perform 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

In the CY 2019 ESRD PPS DMEPOS proposed rule, we noted additional concerns in

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. Even so, 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 under section 1834(a)(3) of the Act, the multi-function ventilator item can be eligible for inclusion in a CBP in the future along with other ventilator items.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on Payment for Multi-Function Ventilators

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed 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 (83 FR 34386). As we noted, 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. We proposed that multi-function ventilators be classified under section 1834(a)(3) of the Act because the statute specifically mandates that ventilators other than continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices be classified under this section. Items classified under section 1834(a)(3) of the Act are paid on a continuous monthly rental basis.

We proposed 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 would 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), and (f) , 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 40: 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 x 36 months) / 60 months*	E1392 + E1390
(b)	CY 1993 Nebulizer monthly rental fee schedule amount x covered item update factor for DME to CY 2019**	E0570
(c)	CY 1993 Suction Pump monthly rental fee schedule amount x 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 would 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 proposed 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 proposed 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 if these separate items are furnished on or after the date that the multi-function ventilator is furnished. Thus, we noted our proposal would prevent 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 (83 FR 34389). Also, this proposed payment method would lessen 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 note, we did not propose to apply proposed § 414.222(f) to other DME items. Subsequent rulemaking would be necessary to address other multi-function items in the future.

For further detailed information, we refer readers to section VIII.C of the CY 2019 ESRD PPS DMEPOS proposed rule.

We received approximately 23 public comments on our proposal from manufacturers, suppliers, beneficiary advocacy groups, and industry representative groups including respiratory associations. The comments on the proposed rule and our responses to the comments are set forth below. We also provide a summary of several comments that were outside the scope of this rulemaking.

Comment: Most commenters supported our proposal to establish a payment methodology for the new technology multi-function ventilator. Commenters support reimbursement for this integrated item that is innovative and improves care for complex beneficiaries and their caregivers in the home and permits improved patient mobility.

Response: We appreciate the support for our proposal. We are finalizing § 414.222(f) to establish a payment method for multi-function ventilators.

Comment: Two commenters recommended that CMS monitor this new payment method to ensure that patients who require all five functions and have a short life expectancy maintain access to the multi-function device. The commenters were concerned that the proposed rule spreads payments for the additional functions performed by the ventilator over 60 months (the reasonable useful lifetime of equipment performing these functions). The commenters explain that certain patients with a life expectancy of 1 or 2 years may require all five therapies, but would not benefit from payment spread over 60 months. The commenters are concerned this shorter life expectancy may not coincide with the payment structure spread over 60 months.

Response: In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed to establish a monthly rental fee schedule amount for the equipment that does not cap consistent with the

mandated payment rule for ventilators and other items classified under section 1834(a)(3) of the Act. Moreover, the supplier never loses title to the equipment, and the supplier can rent the equipment to other beneficiaries once one beneficiary has rented the item for one or two years. As a result, the supplier can receive payment for each rental month and over the duration that the equipment is medically necessary even in cases when the supplier rents the equipment to a beneficiary with a short term need for the equipment. We believe the ability to re-rent the multi-function ventilator to another beneficiary permits a supplier to furnish the item in instances where a beneficiary might only have a short term need and receive payment for the number of months rented.

Comment: Some commenters did not support our proposal for payment of a multi-function ventilator under a methodology which establishes a fee schedule amount. The commenters recommended the item be paid based on the reasonable charge payment method (42 CFR 405.502). The commenters recommended the item be paid under reasonable charge method as use of the item's functions may change based on the beneficiary's medical needs and the commenters recommend that suppliers should bill additional charges for each function utilized on the multi-function ventilator item.

Response: We appreciate this comment. However, as discussed in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34387), the information we gathered during our review supported our proposal to classify the multi-function ventilator item under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, which is the statutory payment category for ventilators other than continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices. Also, section 1834(a)(1)(C) of the Act mandates that payment for DME be based on the lesser of the actual charge for the item or the

payment amount recognized under sections 1834(a)(2) through 1834(a)(7) of the Act (the fee schedule). In coordination with our review of the item and the statutory payment requirements, we believe a monthly rental fee schedule amount can be established for a multi-function ventilator based on the cost of the ventilator function and the average costs of the various additional functions or features for oxygen concentration, drug nebulization, respiratory airway suction, and cough stimulation. This payment method permits a supplier to receive a predictable monthly payment amount from the start of the rental period for a multi-function ventilator. Also, the item will only be covered for beneficiaries that have a medical need for a ventilator and additional function(s).

Final Rule Action: After consideration of comments received and for the reasons we articulated above and in the CY 2019 ESRD PPS DMEPOS proposed rule, we are finalizing § 414.222(f) similar to our proposal to establish a payment methodology for multi-function ventilators effective for dates of service on or after January 1, 2019. However, we are finalizing three minor technical edits to § 414.222(f) to correct for typos. Specifically, we are deleting the extraneous word “of” in two places where it appeared in the proposed regulation text in § 414.222(f)(3)(iii) and (iv) and we are deleting the cross reference to subparagraph “(g)” in § 414.226, as it does not apply.

IX. Northern Mariana Islands in Future National Mail Order CBPs

A. Background

In our CY 2015 ESRD PPS DMEPOS 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. Therefore, at the time we did not consider the Northern Mariana Islands to be an area

eligible for inclusion under a national mail order CBP. We also finalized a fee schedule adjustment methodology based on information from the national mail order program for items and services furnished in 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 SPAs established under a national mail order program.

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”, 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 (71 FR 23996). 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.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on Including the Northern Mariana Islands in Future National Mail Order CBPs

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed 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 (83 FR 34389). Section 414.210(g)(7) currently states that 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. Once the Northern Mariana Islands are included under a national mail order CBP, this part of § 414.210(g)(7) would

be confusing and unnecessary, which is why we proposed 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 (83 FR 34389). We are finalizing this amendment to §414.210(g)(7) because we intend to include the Northern Mariana Islands in the CBA for all competitions under the national mail order CBP beginning on or after January 1, 2019.

We received approximately four public comments on our proposal from suppliers, and industry representative groups; however, none of the suppliers were located in the Northern Mariana Islands. The comments and our responses to those comments are set forth below. .

Comment: The commenters recommended that the Northern Mariana Islands not be included in future National Mail Order CBPs, saying that including the Northern Mariana Islands in future National Mail Order CBPs will create access issues due to increased shipping times, and causing what they believed to be an already at-risk population to face an increased risk.

Response: We do not believe that including the Northern Mariana Islands in a future National Mail Order CBP will limit access. On the contrary, we believe it will help ensure access for the beneficiaries in this area. Including the Northern Mariana Islands under the National Mail Order CBP ensures access to mail order diabetic supplies since suppliers awarded contracts under the program must make the supplies available to any beneficiary in the area who requests the items from the supplier. Because there are a limited number of pharmacies in the Northern Mariana Islands, we believe that adding the Northern Mariana Islands to a future National Mail Order CBP will help ensure access for beneficiaries in Northern Mariana Islands who need diabetic testing supplies. We also do not have any evidence to suggest that implementing the National Mail Order CBP in the Northern Mariana Islands will increase

shipping times. Beneficiaries will also still be able to obtain their diabetic testing supplies from pharmacy storefronts as well, if they so choose. As with all CBPs, we will continue to monitor the National Mail Order CBP for any access issues, including any negative beneficiary health outcomes.

Final Rule Action: After consideration of comments received and for reasons we set forth previously in this final rule and in the CY 2019 ESRD PPS DMEPOS proposed rule, we are finalizing the proposed revision to § 414.210(g)(7) with a minor technical change to the language to denote 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 § 414.210(g)(7) no longer applies. Thus, 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 § 414.210(g)(7) will no longer apply to mail order items furnished to beneficiaries in the Northern Mariana Islands.

X. Summary of the 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 solicited 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.

We received approximately 25 public comments from manufacturers, suppliers, beneficiary advocacy groups, and industry representative groups. The comments received in response to the Request for Information on the Gap-filling Process for Establishing Fees for New DMEPOS Items are set forth below.

Comments: Overall the commenters recommended that CMS increase transparency for stakeholders during the gap-filling process for establishing fees for new DMEPOS items and revise the process for filling the gap in the data due to the lack of historic reasonable charge payments by estimating what the historic reasonable charge payments would have been for the items from a base year of 1986 and 1987 and inflating to the current year. Many commenters recommended discontinuing the application of past Consumer Price Index (CPI) freezes and reductions when establishing new fee schedule amounts for new HCPCS codes. Some commenters recommended that CMS include in its next budget proposal a provision to amend the statute at 42 U.S.C. 1395 to eliminate or modify the 1987 base year requirement for payment for DMEPOS items and 1992 base year requirement for payment for surgical dressing items. Also, some commenters recommended against CMS including internet or catalog pricing in the gap-filling process unless there is evidence that the price meets all Medicare criterion and includes all Medicare required services. The commenters elaborated that Internet and catalog prices do not reflect the costs of the many Medicare supplier requirements such as supplier

accreditation, in-the-home assessment, beneficiary training, and documentation, and therefore, do not contribute to a reasonable payment level. Several commenters suggested developing additional guidelines and definitions for determining whether an item is comparable for the purpose of assigning a fee schedule amount to a new item. The commenters elaborated that in order for an item to be comparable to another item, both should have similar features and function, should be intended for the same patient population, for the same clinical indicators, and to fill the same medical need. In addition, some commenters endorsed the addition of a weighting calculation to apply to a median price to factor in the existing market share of the item. The commenters expressed concern that the current gap-filling methodology assumes that all products within a given HCPCS code have equal characteristics, minimum specifications, and the gap-filling method does not account for relative quality, durability, clinical preference, and overall market demand. Thus, the commenters are concerned that the calculation of a gap-fill amount for a new item does not reflect the utilization experience of an existing item. Two commenters recommended that CMS develop an appeals process in situations where the manufacturer or supplier disagrees with the recommendation of a contractor or a final payment decision by CMS and there is data to support the opposition. One commenter recommended that CMS develop a separate gap-filling process for orthotics and prosthetics items. The commenter described that most orthotic and prosthetic care requires a significant, ongoing patient-clinician relationship which is different from the furnishing of DME, which the commenter stated is typically a one-time or short-term encounter between the home health agency or DME supplier. Finally, two commenters stated changes to the HCPCS coding process are required to establish more codes for new technology DMEPOS items before applying the gap-filling process.

We appreciate the range of the comments we received. We will consider these comments

carefully as we contemplate future policies. We recognize exploring ways to accommodate new technology, accessibility and affordability are important goals while satisfying the exclusive payment rules for DMEPOS 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 proposed 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 proposed to make minor technical amendments as follows:

- In § 414.422, we proposed to correct the numbering in paragraph (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 paragraph (d)(4) contains subsections (i) through (v), including (ii). The content of paragraph (d)(4) would remain the same.
- In § 414.423(i)(8), we proposed to remove the reference to “42 U.S.C.”

before Title 18. This statutory citation was inadvertently included when the regulation was promulgated.

We solicited public comments on these technical amendments. We did not receive any comments, and therefore, we are finalizing as proposed without change. We are finalizing the technical amendments to § 414.422 to correct the numbering so that paragraph (d)(4) contains subsections (i) through (v), including (ii). The content of paragraph (d)(4) would remain the same. We are also finalizing the removal of the reference to “42 U.S.C.” in § 414.423.

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 49105), 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. Final 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 we 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.

As we discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34390), after reviewing 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 proposed 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 proposed to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. This proposal did 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 solicited comment on this proposal. The comments and our responses to the comments on the comorbidity documentation burden reduction proposal are set forth below.

Comment: A national dialysis organization thanked CMS for acknowledging its concerns regarding comorbidity documentation, but indicated the use of ICD Official Guidelines will not sufficiently address this problem. The organization stated the proposed rule is silent on what documentation will be required to support the reporting of comorbid condition ICD-10 codes and pointed out the dialysis facilities do not diagnose patients with these conditions, which means they will continue to have to rely upon documentation from other providers to support the claim. An LDO stated that the use of the ICD Official Guidelines will have no material effect on the root problem dialysis facilities encounter in receiving payments under the comorbidity adjustment.

A dialysis provider organization stated the use of ICD-10 codes to document comorbidities is an improvement over the current documentation requirements, since both pericarditis and hemolytic anemia (including sickle cell anemia) are more likely to be captured as a routine matter by ESRD providers than the current requirements. However, the commenter pointed out gastrointestinal tract bleeding with hemorrhage is not a diagnosis for which a dialysis clinic has ready access to the necessary documentation and when a hospital admission is involved, gathering the required supporting documentation such as from a colonoscopy or endoscopy, can be difficult, if not impossible. The commenter questioned whether these

comorbidities are appropriate to begin with from both clinical, as well as cost vantage points. The commenter stated that from a clinical vantage point, cardiovascular disease, which is not among the current comorbidities is a, if not the, leading cause of death in the ESRD population. The commenter stated the ESRD PPS outlier policy can help address disproportionate costs associated with comorbidities and, since the Secretary has discretion as to what may be included in the case mix adjustment, CMS should consider suspending use of comorbidities.

An LDO expressed appreciation for the proposal to no longer require ESRD facilities obtain results from specific diagnostic tests in order to qualify for a comorbidity payment adjustment and to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. The LDO stated CMS's assumption that the patient's diagnosing physician would provide the documentation is not accurate. In the majority of the cases, the LDO asserted, coding for the comorbidities is performed by hospital system professional coders at the time of a hospital discharge by reading through a patient's chart. In most cases the treating physicians are hospitalists, and they are unfamiliar with ESRD policies about comorbidities and payment. Furthermore, the LDO sees no reason to obtain more results to get to the granularity of the ICD-10 code currently required to support ESRD comorbidity reporting, because the LDO believes that in many or most cases, this diagnostic information will not change the treatment course.

Response: We appreciate the feedback from commenters on our proposal to rely on ICD Official Guidelines. We continue to believe it is important for ESRD facilities to be aware of patients' conditions. The CfCs for ESRD facilities at § 494.80(a)(1) indicates a patient's comprehensive assessment must include evaluation of current health status and medical condition, including co-morbid conditions. For the purpose of receiving a payment adjustment, the appropriate ICD-10-CM codes are required to be present on the claim with the appropriate

documentation as required by ICD official guidelines in the patient's medical record.

We also continue to believe obtaining the medical documentation necessary to receive payments should not be complicated or burdensome, and is important for care coordination purposes. In situations where the patient's medical record is incomplete and the ESRD facility is unable to obtain the documentation needed to report the comorbidity diagnosis, we would expect the facility to include the cost for all outlier-eligible services on the claim and qualify for an outlier payment when the cost exceeds the outlier fixed dollar loss threshold. This approach supports access to dialysis for high cost patients. We will continue to monitor the extent to which the comorbidities are reported.

Comment: Several commenters expressed concern regarding the availability of the documentation needed to support the reporting of the diagnosis code describing the comorbidity eligible for the adjustment and provided suggestions on how to streamline the process.

Some commenters indicated that the documentation is rarely, if ever, available because CMS does not require the other providers to disclose the information to dialysis facilities. An LDO stated that despite its best attempts in following up with other providers, the organization has encountered challenges in receiving discharge instructions/summaries, pending laboratory results, and other relevant information on their patients. The LDO asserted that to ensure effective care delivery, patient safety, and the application of a revised, valid and reliable comorbidity adjuster, CMS should require hospitals, particularly those using certified health information technology, to send the following information to other providers involved in an ESRD patient's care: (1) discharge instructions and discharge summary within 48 hours; (2) pending test results within 72 hours of their availability; and (3) all other necessary information specified in the "transfer to another facility" requirements.

One health plan encouraged CMS to reduce documentation burden by automatically incorporating diagnosis codes from all claims (that is, hospital and physician claims in addition to ESRD claims) when determining if a comorbidity adjustment applies. The health plan explained that ESRD facilities struggle to obtain documentation from other providers in order to include the diagnosis on the ESRD claim, even when the ESRD facility has a common electronic health record with the hospital and physician practice. The health plan noted that because the diagnosis coding does not automatically transfer to the ESRD medical record the hospital medical record has to be thoroughly reviewed to determine the appropriate diagnosis codes to enter on the ESRD claim. The health plan believes automation within CMS's system would create a more seamless and accurate application of the comorbidity adjustment.

One dialysis provider organization requested that CMS use claims data in addition to the ICD Guidelines for Coding and Reporting to identify comorbidities present in patients eligible for payment adjustments. The organization believes the supplementing of ICD coding information with claims data will ensure more accurate payment to providers, as well as further ease administrative burden. As part of this effort, the organization would welcome the opportunity to work with CMS to help educate dialysis providers on how to code patient comorbidities on their claims.

Response: We appreciate the requests for interoperability with other care settings either through electronic health records or claims data and agree that it could reduce the burden related to comorbidity documentation. We will consider these for future updates and will coordinate with other federal partners, as feasible.

Comment: MedPAC commented CMS should consider removing all comorbidity payment adjustments used in the current ESRD PPS because these adjustment factors may not be

estimated accurately. A MedPAC analysis showed the comorbid conditions are poorly identified on dialysis claims and reflect only differences in the cost of dialysis services formerly separately billable. MedPAC further stated that to the extent unreported comorbid conditions increase the cost of treatment above the ESRD PPS base rate, those costs are currently borne by the facility and the outlier payment pool.

An LDO stated CMS's proposal to have facilities document different criteria does not change the fundamental challenge with claiming case mix adjusters. The LDO recommended CMS follow the long-standing recommendations of the kidney community and MedPAC and eliminate the comorbid case mix adjusters from the ESRD PPS in the CY 2019 ESRD PPS final rule.

A national dialysis organization, in its comment on the outlier expansion solicitation, recommended CMS address the comorbidity documentation burden by relying upon the outlier payments for the higher costs it assumes are addressed through the comorbid case-mix adjusters. The organization expressed concern that these adjusters do not actually reflect higher cost patients and that money is being taken out of the system that is never returned to support patient care. Additionally, the organization stated outlier payments would be sufficient to address the higher costs related to patients with these conditions. Instead, the organization recommended that CMS eliminate the comorbid case-mix adjusters for CY 2019 and recognize any patient with one of the remaining conditions would use more of the drugs currently eligible for the outlier payment.

A national provider organization also urged CMS to eliminate comorbidity adjustments from the payment system until CMS develops appropriate adjusters that accurately capture variance in costs of care for particularly high-cost, high-acuity patients. The organization agrees

with CMS that the cost of dialysis treatment varies depending on the volume of services provided at the facility, its location and the adult and pediatric patients it serves, and thus appreciates appropriate adjustments in the payment system that account for these differences in cost of care. However, the organization stated the existing comorbidity adjustments in the ESRD PPS do not correspond well with the significant variance in costs facilities experience in treating patients with certain particularly complex and costly comorbidities and other acute illness or trauma events. As a result, the organization believes the current comorbidity adjustments inappropriately take away funding from the ESRD base rate that otherwise could support provision of high-quality care. An LDO recommended removing the remaining comorbid adjusters; and if not removed, they should be adjusted. Another LDO advised CMS to add more generic codes to the list including:

K29.51 Unspecified chronic gastritis with bleeding

K29.61 Other gastritis with bleeding

K29.71 Gastritis, unspecified, with bleeding

K29.91 Gastroduodenitis, unspecified, with bleeding

K92.2 Gastrointestinal hemorrhage, unspecified

A professional association expressed concern that, without a clear, simple process to obtain detailed comorbid condition data and the ability to document these data for submission to CMS, comorbid conditions impacting the ESRD PPS bundled payment will continue to be insufficiently documented. Consequentially, funds set aside for care of dialysis patients will not be expended. The association expressed that it is inappropriate to have funds set aside to improve care for the most complex patients remain unused due to a documentation hurdle, ultimately missing an opportunity to improve the lives of dialysis patients.

Response: We acknowledge that some commenters would prefer comorbidity adjusters be removed from the payment system with the dollars returned to the base rate and allow more expensive care for certain patients be addressed through the outlier policy. As we discussed in the CY 2016 ESRD PPS final rule (80 FR 68981 through 68982), the comorbidity adjusters have economically meaningful multipliers so we will continue to include them in the payment system. We will, however, consider this feedback.

With regard to the commenter's suggestion on adding more generic diagnosis codes to the list of comorbidities eligible for the payment adjustment, we would like to refer the commenter to the CY 2011 ESRD PPS final rule (75 FR 49095) where we discuss the exclusion criteria used when determining the eligible diagnosis codes. Specifically, we explained that based on various issues and concerns raised in public comments regarding the proposed comorbidity categories recognized for a payment adjustment, we further evaluated the co-morbidity categories with regard to: (1) Inability to create accurate clinical definitions; (2) potential for adverse incentives regarding care; and (3) potential for ESRD facilities to directly influence the prevalence of the co-morbidity either by altering dialysis care, diagnostic testing patterns, or liberalizing the diagnostic criteria. We believe that unspecified codes would meet the first criteria since the code would not provide an accurate description of the active condition. Additionally, in that rule (75 FR 49108), we finalized eliminating diagnostic codes identified in Table 16 of the CY 2011 ESRD PPS proposed rule (74 FR 49956) described as unspecified, not otherwise specified, or not elsewhere specified, since these codes are general and do not provide meaningful identification of a disease. With this information in mind, we believe the diagnosis codes suggested by the commenter would meet the exclusion criteria and would exclude them from being eligible for a payment adjustment.

We remain concerned eliminating the comorbidity categories may result in access to care issues. We continue to believe the payment model aligns with our goals for the PPS in establishing accurate payments and safeguarding access for Medicare beneficiaries. We plan to continue to monitor the reporting of diagnosis codes and are conducting research on potential future refinements. Additionally, we are undertaking a new research effort and plan to engage with stakeholders further on this issue

Final Rule Action: After considering the public comments, we are finalizing the proposal to rely on ICD Official Guidelines and general documentation requirements to receive the comorbidity payment adjustment without change.

XIII. Requests for Information

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

In the CY 2019 ESRD PPS proposed rule (83 FR 34304 through 34415), we included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. We received approximately 9 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2019 ESRD PPS proposed rule (83 FR 34304 through 34415), we included a Request for Information (RFI) related to price transparency and improving beneficiary access to provider and supplier charge information. We received approximately 8 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

XIV. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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. We solicited comments in the notice of proposed rulemaking that published in the **Federal Register** on July 19, 2018 (83 FR 34304 through 34415). For the purpose of transparency, we are republishing the discussion of the information collection requirements. All of the requirements discussed in this section are already accounted for in OMB approved information collection requests.

B. Requirements in Regulation Text

In sections II.B.1 and II.B.2.b of this final rule, we are finalizing changes to regulatory text for the ESRD PPS in CY 2019. We are also finalizing changes to regulatory text for the ESRD QIP in section IV.A.3 of this final rule. However, the changes that are being finalized do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. 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 data²⁹, 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.³⁰ 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 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

²⁹ <https://www.bls.gov/oes/current/oes292071.htm>.

³⁰ <https://www.bls.gov/oes/current/oes291141.htm>.

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 final rule outlines the new data validation policies that we are finalizing for the ESRD QIP. Specifically, for the CROWNWeb validation, we are finalizing a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we will use to validate CROWNWeb data for all payment years, beginning with PY 2021. Under this methodology, 300 facilities will be selected each year to submit to CMS not more than 10 records, and we will 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 will 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 will be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately \$30,885 (750 hours x \$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 continued study for validating data reported to the NHSN Dialysis Event

Module, we are finalizing a modification of the sampling methodology that we previously finalized in the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767). Under the finalized modifications, we will 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 will 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 will take each facility approximately 10 hours to comply with this requirement. We also estimate that in PY 2021, the total combined annual burden for the 150 facilities asked to submit records will be 1,500 hours (150 facilities x 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2021 will be \$61,770 (1,500 hours x \$41.18), or a total of approximately \$412 (\$61,770/150 facilities) per facility in the sample in PY 2021. We finalized a policy to ask 300 facilities to submit records for PY 2022, and we estimate that the total combined annual burden for these facilities will be 3,000 hours (300 facilities x 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2022 would be \$123,540 (3,000 hours x \$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. New CROWNWeb Reporting Requirements for PY 2021 and PY 2022

To determine the burden associated with the 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 will 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 final rule, we are finalizing a policy to modify our data collection requirements for PY 2021 by removing four reporting measures from the ESRD QIP measure set. These changes will 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 removal of the Pain Assessment and Follow-Up reporting measure and the remaining \$10 million of that reduction is attributable to the 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 removal of the Pain Assessment and Follow-Up reporting measure and the remaining 260,000 hours of that reduction is attributable to the removal of the Serum Phosphorus reporting measure. The removal of the other two reporting measures (Healthcare Personnel Influenza Vaccination and Anemia Management) will not affect our burden calculations because data on those measures are not reported through CROWNWeb.

In section IV.C.1 of this final rule, we are finalizing policies to adopt two new measures beginning with PY 2022. We estimate that the burden associated with this new data collection requirement will be approximately \$21 million, or an estimated 510,000 burden hours, and that this burden will 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 will be no additional burden on facilities related to the PPPW measure.

We estimate that the total burden increase associated with reporting data on the two new measures finalized 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 the CY 2019 ESRD PPS proposed rule, we proposed to adopt one new measure beginning in PY 2024. We estimated that the burden associated with the proposed measure will be zero. Since facilities would not have been required to submit data to CROWNWeb for the SWR measure, we estimated that there would be no burden in connection with this measure in PY 2024. We are not finalizing this proposal.

3. DMEPOS Competitive Bidding Program

a. Bidding Forms A and B

Section V.D.1 of this final rule outlines our 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 CBP 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 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 of bidding, 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 estimated 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 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 anticipated 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 sought comments on this assumption and we did not receive any comments. We estimated, 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 (\$99.40 x 8 hours and 21 minutes). 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 assumed that the number of bidders would be roughly the same

as in previous rounds of competition. We estimated 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 assumed the average bidder would bid in 5 CBAs in 7 product categories for an average total of 35 Form Bs. We expected 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 change in bidding methodology to move to lead item pricing as described in section V.D.1 of this final 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 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 anticipated 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 estimated it would require the average bidder 105 hours to complete all 35 Form Bs with a cost of \$10,437 ($\99.40×105 hours). Assuming 1,500 bidders

participate in the next round of the DMEPOS CBP, and each bidder completes 35 Form Bs, there would be an estimated 52,500 Form Bs submitted taking an estimated 157,500 hours for a total estimated cost of \$15,655,500 (\$99.40 x 157,500 hours).

The information collection request associated with the DMEPOS CBP will be revised and submitted to OMB under control number 0938-1016. The requirement to use Forms A and B when bidding in the next round of the DMEPOS CBP will not be effective until the two forms are approved by OMB.

XV. 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 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 regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. We solicited comments on the regulatory impact analysis provided, and we received 1 comment, which we discuss in section XVI of this final rule.

2. Statement of Need

a. ESRD PPS

This rule finalizes a number of routine updates and several policy changes to the ESRD PPS in CY 2019. The finalized 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 final rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to ESRD beneficiaries.

b. AKI

This rule also finalizes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final 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 finalized policies to implement requirements for the ESRD QIP, including the adoption of two new measures beginning with PY 2022. Failure to finalize requirements for the PY 2022 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2021. In addition, finalizing 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 final 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 finalizes revisions to the definitions of “bid” and “composite bid” and establishes a new definition for “lead item.”

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

We are finalizing 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, we are finalizing 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 made consistent with the rules in place as of January 1, 2018.

The impacts are expected to cost \$1.05 billion 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 final rule amends our regulations at § 414.226 by revising the payment rules for oxygen and oxygen equipment and adding a new paragraph 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 are establishing two classes for portable oxygen equipment: (1) one class for gaseous tanks, and (2) another class for liquid tanks. We are also finalizing an additional class for liquid oxygen contents for prescribed flow rates greater than 4 liters per minute and used with portable equipment. We are also finalizing 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 finalizing a payment rule in § 414.222(f) for multi-function ventilators that establishes 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. Northern Mariana Islands in Future National Mail Order CBPs

We are finalizing an amendment to § 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 no longer applies.

3. Overall Impact

a. ESRD PPS

We estimate that the finalized revisions to the ESRD PPS will result in an increase of approximately \$210 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. These payments represent transfers from the Federal Government to ESRD providers (\$160 million) and transfers from the beneficiaries to ESRD providers (\$50 million).

b. AKI

We are estimating approximately \$40 million will 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 for this final rule with updated wage estimates, facility counts, and patient counts, as well as the policy changes described earlier in the preamble of this final rule, including the measure removals and measure weighting changes. We also re-estimated the payment reductions under the ESRD QIP in accordance with the policy changes described earlier, including the domain restructuring and reweighting. We estimate that these updates will result in an overall impact of \$213 million associated with quality reporting burden and payment reductions, which includes a \$12 million incremental reduction in burden in collection of information requirements and \$32 million in estimated payment reductions across all facilities. PY 2021 ESRD QIP payment reductions represent transfers from the federal government to ESRD providers of -\$32 million, and total ESRD provider costs under the ESRD QIP for PY 2021 total \$181 million.

For PY 2022, we estimate that the proposed revisions to the ESRD QIP will result in an increase in overall impact to \$234 million, which includes a \$21 million incremental increase associated with the collection of information requirements and \$32 million in estimated payment reductions across all facilities. PY 2022 ESRD QIP payment reductions represent transfers from the federal government to ESRD providers of -\$32 million, and total ESRD provider costs under the ESRD QIP for PY 2022 total \$202 million.

d. DMEPOS

Impacts are generally considered against the Medicare, Medicaid and beneficiary cost sharing. A special consideration of impacts is made in Table 50 wherein impacts are considered as transfer amounts based on annualized value against two different interest rates.

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

Competitive Bidding Program (CBP)

We estimate that the finalized revisions to base SPAs 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) will cost about \$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

We are finalizing 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, we are finalizing 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 made consistent with the rules in place as of January 1, 2018.

The impacts are expected to cost \$1.05 billion 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 rule finalizes new payment classes for oxygen and oxygen equipment and is estimated to be budget neutral to the Medicare program. However, the new payment classes may result in overall slightly increased beneficiary cost-sharing.

iv. Payment for Multi-Function Ventilators

This final rule establishes 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 \$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 beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be \$0 million.

v. Northern Mariana Islands in Future National Mail Order CBPs

This change will 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 final 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 final rule

will be the number of reviewers of this final 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 final 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 welcomed comments on the approach in estimating the number of entities which will review this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption. We did not receive any comments on this section of the rule.

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 final rule. For each ESRD facility that reviews the rule, the estimated cost is \$687.50 (6.25 hours x \$110.00). Therefore, we estimate that the total cost of reviewing this regulation rounds to \$39,875. (\$687.50 x 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 final rule. For each entity that reviews this final rule, the estimated cost is \$220.00 (2 hours x \$110.00). Therefore, we estimate that the total cost of reviewing this final rule is \$143,000 (\$220.00 x 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 final rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of August 3, 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 of this final rule. Table 41 shows the impact of the estimated CY 2019 ESRD payments compared to estimated payments to ESRD facilities in CY 2018.

TABLE 41: Impact of Finalized Changes in Payment to ESRD Facilities for CY 2019¹

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2019 Changes in Outlier Policy (%) C	Effect of 2019 Changes in Wage Index, Wage Floor, and Labor-related Share (%) D	Effect of 2019 Changes in payment rate update (%) E	Effect of Total 2019 Final Changes (%) F
All Facilities	7,099	45.1	0.3	0.0	1.3	1.6
Type						
Freestanding	6,681	43.0	0.3	0.0	1.3	1.6
Hospital based	418	2.2	0.6	-0.1	1.3	1.7
Ownership Type						
Large dialysis organization	5,400	34.9	0.3	-0.1	1.3	1.6
Regional chain	881	5.7	0.4	0.1	1.3	1.9
Independent	485	2.9	0.4	0.2	1.3	1.9
Hospital based ²	327	1.7	0.6	-0.1	1.3	1.8
Unknown	6	0.0	0.2	0.4	1.2	1.8
Geographic Location						
Rural	1,271	6.5	0.3	-0.3	1.3	1.3
Urban	5,828	38.6	0.3	0.1	1.3	1.7
Census Region						
East North Central	1,145	6.3	0.3	-0.4	1.3	1.3
East South Central	572	3.3	0.3	-0.7	1.3	1.0
Middle Atlantic	777	5.5	0.4	0.1	1.3	1.7
Mountain	400	2.3	0.2	-0.4	1.3	1.1
New England	191	1.5	0.3	-0.4	1.3	1.2
Pacific ³	845	6.5	0.3	1.1	1.3	2.7
Puerto Rico and Virgin Islands	51	0.3	0.1	4.5	1.3	6.0
South Atlantic	1,622	10.6	0.4	-0.3	1.3	1.4
West North Central	497	2.3	0.4	-0.3	1.3	1.3
West South Central	999	6.6	0.3	0.0	1.3	1.6
Facility Size						
Less than 4,000 treatments	1,246	2.1	0.3	-0.2	1.3	1.5
4,000 to 9,999 treatments	2,666	11.9	0.4	-0.2	1.3	1.5
10,000 or more treatments	3,147	31.0	0.3	0.1	1.3	1.7
Unknown	40	0.2	0.6	0.3	1.3	2.2
Percentage of Pediatric Patients						
Less than 2	6,993	44.8	0.3	0.0	1.3	1.6
Between 2 and 19	41	0.3	0.4	0.1	1.3	1.8
Between 20 and 49	11	0.0	0.1	-0.2	1.3	1.2
More than 50	54	0.0	-0.1	0.1	1.3	1.4

¹ Calcimimetics 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.

²Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

³Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands

Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

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 final changes to the outlier payment policy described in section II.B of this final 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 0.3 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 finalized CY 2019 wage indices, the wage index floor of 0.50, and the updated labor-related share. 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 final updates.

Column E shows the effect of the finalized CY 2019 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.3 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2019 of 2.1 percent and the final MFP adjustment of 0.8 percent.

Column F reflects the overall impact, that is, the effects of the finalized outlier policy changes, wage index floor, labor-related share, and payment rate update. We expect that overall ESRD facilities will experience a 1.6 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 1.0 percent to 6.0 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 finalized ESRD PPS payment rate will 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 will be approximately \$10.5 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 2.0 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 1.6 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 1.6 percent in CY 2019, which translates to approximately \$50 million.

e. Alternatives Considered

In section II.B.3 of this final rule, we finalized a new wage index floor of 0.50. In establishing the new wage index floor, we considered maintaining the existing wage index floor of 0.40 and also considered increasing the wage floor to 0.51 and 0.55. However, based on the analyses we have conducted, we no longer believe a wage index floor value of 0.40 is appropriate and we are concerned about the impact a higher floor value than .50 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 final rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of August 3, 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 of this final rule. Table 42 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 42: Impact of Finalized Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2019

Facility Type	Number of Facilities A	Number of Treatments (in thousands) B	Effect of 2019 Changes in Wage Index, Wage Floor, and Labor-related Share (%) C	Effect of 2019 Changes in payment rate update (%) D	Effect of Total 2019 Final Changes (%) E
All Facilities	3,930	163.7	0.0	1.3	1.3
Type					
Freestanding	3,837	160.3	0.0	1.3	1.3
Hospital based	93	3.4	-0.1	1.3	1.2
Ownership Type					
Large dialysis organization	3,318	139.7	0.0	1.3	1.3
Regional chain	426	16.6	-0.0	1.3	1.3
Independent	125	4.8	0.0	1.3	1.4
Hospital based ¹	61	2.7	-0.1	1.3	1.2
Unknown	0	0.0	0.0	0.0	0.0
Geographic Location					
Rural	703	26.6	-0.3	1.3	1.0
Urban	3,227	137.1	0.1	1.3	1.4
Census Region					
East North Central	718	31.2	-0.3	1.3	1.0
East South Central	315	11.3	-0.6	1.3	0.8
Middle Atlantic	406	17.4	0.0	1.3	1.3
Mountain	248	11.3	-0.4	1.3	0.9
New England	126	4.9	-0.4	1.3	1.0
Pacific ²	486	27.7	1.1	1.3	2.5
Puerto Rico and Virgin Islands	2	0.0	5.9	1.3	7.3
South Atlantic	889	35.7	-0.4	1.3	1.0
West North Central	255	7.8	-0.3	1.3	1.0
West South Central	485	16.3	-0.1	1.3	1.2
Facility Size					
Less than 4,000 treatments	394	11.4	0.0	1.3	1.4
4,000 to 9,999 treatments	1,538	58.0	-0.1	1.3	1.2
10,000 or more treatments	1,990	93.9	0.1	1.3	1.4
Unknown	8	0.4	0.6	1.3	1.9
Percentage of Pediatric Patients					
Less than 2	3,929	163.5	0.0	1.3	1.3
Between 2 and 19	0	0.0	0.0	0.0	0.0
Between 20 and 49	0	0.0	0.0	0.0	0.0
More than 50	1	0.2	0.6	1.3	1.9

¹Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

²Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands

Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

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 final CY 2019 wage indices, the wage index floor of 0.50, and the updated labor-related share. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.0 percent to a 5.9 percent increase due to these final updates.

Column D shows the effect of the final CY 2019 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.3 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2019 of 2.1 percent and the final MFP adjustment of 0.8 percent.

Column E reflects the overall impact, that is, the effects of the final wage index floor, labor-related share, and payment rate update. We expect that overall ESRD facilities would experience a 1.3 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 7.3 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 updating 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 \$40.0 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 will 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 will 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 2021 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 finalizing to use to determine a facility's TPS for the PY 2021 ESRD QIP is described in section IV.C of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2021 ESRD QIP will apply to ESRD PPS payments made to the facility for services furnished in CY 2021.

For the PY 2021 ESRD QIP, we estimate that of the 7,042 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 46.01 percent or 3,240 of the facilities would receive a payment reduction for PY 2021. The total payment reduction for all of the 3,240 facilities expected to receive a reduction is approximately \$32,196,724. Facilities that do not receive a TPS do not receive a payment reduction. Additionally, we estimate that the proposed removal of four reporting measures beginning with PY 2021 will reduce the information collection burden by \$12 million.

Table 43 shows the overall estimated distribution of payment reductions resulting from the PY 2021 ESRD QIP.

TABLE 43: Estimated Distribution of PY 2021 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	3,802	56.10%
0.5%	1,532	22.61%
1.0%	896	13.22%
1.5%	359	5.30%
2.0%	188	2.77%

Note: This table excludes 256 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 2021, 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 44.

TABLE 44: Data Used to Estimate PY 2021 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 2016-Dec 2016	Jan 2017-Dec 2017
Hypercalcemia	Jan 2016-Dec 2016	Jan 2017-Dec 2017
STrR	Jan 2015-Dec 2015	Jan 2016-Dec 2016
ICH CAHPS Survey	Jan 2016-Dec 2016	Jan 2017-Dec 2017
SRR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
NHSN BSI	Jan 2016-Dec 2016	Jan 2017-Dec 2017
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 final rule. Facility reporting measure scores were estimated using available data from CY 2016 and 2017. Facilities were required to have a score on at least one measure in any two out of the four domains to receive a TPS.

To estimate the total payment reductions in PY 2021 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 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 2017 through December 2017 times the estimated

payment reduction percentage.

Table 45 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2021. The table also 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 are finalizing to use for the PY 2021 ESRD QIP, the actual impact of the PY 2021 ESRD QIP may vary significantly from the values provided here.

TABLE 45: Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2021

	Number of Facilities	Number of Treatments 2017 (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	7,042	44.5	6,777	2,975	-0.38%
Facility Type:					
<i>Freestanding</i>	6,626	42.4	6,415	2,728	-0.35%
<i>Hospital-based</i>	416	2.1	362	247	-0.79%
Ownership Type:					
<i>Large Dialysis</i>	5,355	34.4	5,208	2,096	-0.32%
<i>Regional Chain</i>	871	5.7	841	388	-0.38%
<i>Independent</i>	479	2.9	447	286	-0.68%
<i>Hospital-based (non-chain)</i>	325	1.6	280	204	-0.88%
<i>Unknown</i>	12	0.0	1	1	-0.50%
Facility Size:					
<i>Large Entities</i>	6,226	40.0	6,049	2,484	-0.33%
<i>Small Entities¹</i>	804	4.5	727	490	-0.75%
<i>Unknown</i>	12	0.0	1	1	-0.50%
Rural Status:					
1) Yes	1,263	6.4	1,221	350	-0.23%

	Number of Facilities	Number of Treatments 2017 (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)
2) No	5,779	38.1	5,556	2,625	-0.41%
Census Region:					
<i>Northeast</i>	960	6.9	917	427	-0.42%
<i>Midwest</i>	1,628	8.5	1,559	625	-0.34%
<i>South</i>	3,168	20.2	3,048	1,491	-0.42%
<i>West</i>	1,228	8.5	1,195	381	-0.26%
<i>US Territories²</i>	58	0.4	58	51	-1.03%
Census Division:					
<i>Unknown</i>	7	0.1	7	5	-1.00%
<i>East North Central</i>	1,136	6.2	1,089	475	-0.37%
<i>East South Central</i>	569	3.3	553	225	-0.31%
<i>Middle Atlantic</i>	769	5.4	733	372	-0.46%
<i>Mountain</i>	398	2.3	386	101	-0.21%
<i>New England</i>	191	1.5	184	55	-0.23%
<i>Pacific</i>	830	6.3	809	280	-0.28%
<i>South Atlantic</i>	1,612	10.4	1,551	822	-0.46%
<i>West North Central</i>	492	2.3	470	150	-0.27%
<i>West South Central</i>	987	6.5	944	444	-0.40%
<i>US Territories²</i>	51	0.3	51	46	-1.03%
Facility Size (# of total treatments)					
<i>Less than 4,000 treatments</i>	1,689	5.9	1,478	731	-0.49%
<i>4,000-9,999 treatments</i>	2,502	11.8	2,493	920	-0.29%
<i>Over 10,000 treatments</i>	2,776	26.7	2,773	1,294	-0.38%
<i>Unknown</i>	75	0.2	33	30	-1.22%

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 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

finalizing to use to determine a facility’s TPS for the PY 2022 ESRD QIP is described in section IV.C of this final rule. Any reductions in ESRD PPS payments as a result of a facility’s performance under the PY 2022 ESRD QIP will 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 7,042 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 43.34 percent or 2,937 of the facilities would receive a payment reduction for PY 2022. The total payment reduction for all of the 2,937 facilities expected to receive a reduction is approximately \$31,624,158.67. Facilities that do not receive a TPS do not receive a payment reduction.

Table 46 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

TABLE 46: Estimated Distribution of PY 2022 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	3,840	56.66%
0.5%	1,535	22.65%
1.0%	872	12.87%
1.5%	352	5.19%
2.0%	178	2.63%

Note: This table excludes 265 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 47.

TABLE 47: 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 2016-Dec 2016	Jan 2017-Dec 2017
Hypercalcemia	Jan 2016-Dec 2016	Jan 2017-Dec 2017
STrR	Jan 2015-Dec 2015	Jan 2016-Dec 2016
ICH CAHPS Survey	Jan 2016-Dec 2016	Jan 2017-Dec 2017
SRR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
NHSN BSI	Jan 2016-Dec 2016	Jan 2017-Dec 2017
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 final rule. Facility reporting measure scores were estimated using available data from CY 2016 and 2017. Facilities were required to have a score on at least one measure in any two out of the four domains to receive a TPS.

To estimate the total payment reductions in PY 2022 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 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 2017 through December 2017 times the estimated

payment reduction percentage.

Table 48 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 are finalizing 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 48: Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2022

	Number of Facilities	Number of Treatments 2017 (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)
<i>All Facilities</i>	7,042	44.5	6,777	2,937	-0.37%
<i>Facility Type:</i>					
<i>Freestanding</i>	6,626	42.4	6,415	2,691	-0.34%
<i>Hospital-based</i>	416	2.1	362	246	-0.78%
<i>Ownership Type:</i>					
<i>Large Dialysis</i>	5,355	34.4	5,208	2,065	-0.31%
<i>Regional Chain</i>	871	5.7	841	383	-0.37%
<i>Independent</i>	479	2.9	447	285	-0.66%
<i>Hospital-based (non-chain)</i>	325	1.6	280	203	-0.87%
<i>Unknown</i>	12	0.0	1	1	-0.50%
<i>Facility Size:</i>					
<i>Large Entities</i>	6,226	40.0	6,049	2,448	-0.32%
<i>Small Entities¹</i>	804	4.5	727	488	-0.74%
<i>Unknown</i>	12	0.0	1	1	-0.50%
<i>Rural Status:</i>					
1) <i>Yes</i>	1,263	6.4	1,221	346	-0.22%
2) <i>No</i>	5,779	38.1	5,556	2,591	-0.40%
<i>Census Region:</i>					
<i>Northeast</i>	960	6.9	917	421	-0.40%
<i>Midwest</i>	1,628	8.5	1,559	614	-0.33%
<i>South</i>	3,168	20.2	3,048	1,481	-0.41%
<i>West</i>	1,228	8.5	1,195	369	-0.25%
<i>US Territories²</i>	58	0.4	58	52	-1.03%
<i>Census Division:</i>					
<i>Unknown</i>	7	0.1	7	5	-0.92%
<i>East North Central</i>	1,136	6.2	1,089	465	-0.36%
<i>East South Central</i>	569	3.3	553	221	-0.30%
<i>Middle Atlantic</i>	769	5.4	733	369	-0.45%
<i>Mountain</i>	398	2.3	386	98	-0.20%
<i>New England</i>	191	1.5	184	52	-0.22%
<i>Pacific</i>	830	6.3	809	271	-0.27%
<i>South Atlantic</i>	1,612	10.4	1,551	822	-0.46%
<i>West North Central</i>	492	2.3	470	149	-0.27%
<i>West South Central</i>	987	6.5	944	438	-0.40%
<i>US Territories²</i>	51	0.3	51	47	-1.04%
<i>Facility Size (# of total treatments)</i>					
<i>Less than 4,000 treatments</i>	1,689	5.9	1,478	718	-0.48%
<i>4,000-9,999 treatments</i>	2,502	11.8	2,493	907	-0.29%
<i>Over 10,000 treatments</i>	2,776	26.7	2,773	1,282	-0.37%
<i>Unknown</i>	75	0.2	33	30	-1.22%

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.

c. 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.

d. Effects on the Medicare Program

For PY 2022, we estimate that ESRD QIP will contribute approximately \$31,624,159 in Medicare savings. For comparison, Table 49 shows the payment reductions that we estimate will be achieved by the ESRD QIP from PY 2017 through PY 2022. We note that we have updated the PY 2021 payment reduction estimate that we published in the CY 2018 ESRD PPS final rule (82 FR 50795).

TABLE 49: Estimated Payment Reductions Payment Year 2017 through 2022

Payment Year	Estimated Payment Reductions (citation)
PY 2022	\$31,624,159
PY 2021	\$32,196,724
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)

e. 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 final rule, we are finalizing 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 finalizing 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.

f. Alternatives Considered

As discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34405) and in section IV.B.3.b of this final rule, we proposed 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), (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).

We had proposed the second alternative in the CY 2019 ERD PPS proposed rule as our weighting redistribution policy. However, in response to concerns raised by public commenters that the STrR measure's weight will comprise a significant share of the TPS for some facilities, and that facilities that predominantly or exclusively care for patients that dialyze at home will be scored predominantly on only a handful of measures, we are not finalizing our proposed weight redistribution policy. Instead, we are finalizing that if a facility does not receive a score on any of the measures in a domain, then that domain's weight will be redistributed evenly across the remaining domains, and then evenly across the measures within each of those domains on which the facility receives a score. Additionally, if a facility receives a score on some, but not all, of the measures within a domain, the weight of the measure(s) for which a score is missing will be redistributed evenly across the other measures in that domain.

The weighting redistribution policy we are finalizing differs from the two policy alternatives discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34342). We are not finalizing our proposed weight redistribution policy because we agree with commenters' concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures. We also reconsidered the policy alternative discussed in the CY 2019 ESRD PPS proposed rule but believe that this policy alternative would not maintain the Meaningful

Measures Initiative priorities in measure weights as effectively as we prefer.

We then considered how best to address commenters' concerns while maintaining the Meaningful Measures Initiative priorities and determined that the policy we are finalizing accomplishes this objective. Our finalized policy maintains the Meaningful Measures Initiative priorities and our preferred emphasis on those topic areas because when a facility is not scored on a measure, the domain weights will be the same as the domain weights of a complete measure set (unless an entire domain's worth of measures is missing, in which case the domain's weight would be redistributed across the remaining domains; for example, if a facility did not receive an ICH CAHPS score, one-third of the Patient & Family Engagement Domain's weight of 15 percent would be distributed to each of the three remaining domains). Our finalized policy also addresses commenters concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures because the weight of measures for which a facility does not receive a score is redistributed evenly within its domain rather than proportionately across the entire measure set; measures with high weights will not receive the largest share of redistributed weights.

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 for the lead item. Therefore, we believe that this final rule will have a positive economic impact on bidding suppliers.

ii. Effects on the Medicare Program

The effect of this rule, which finalizes our proposal to base SPAs 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 rule 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.

As noted in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34358), 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 final rule may be underestimated.

iii. Effects on Medicare Beneficiaries

This final rule will base SPAs 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 we considered but did not propose was 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 finalized fee schedule adjustment methodology for items and services furnished in former CBAs will adjust the fee schedule amounts for such items and services based on the current SPAs plus a CPI-U update. We understand this final rule to be consistent with the requirements of section 1834(a)(1)(F) of the Act. The suppliers furnishing items in areas that are currently non-CBAs will be paid based on adjusted fee schedule amounts.

i. Effects on the Medicare Program

This rule finalizes 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 finalizes 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 \$1.05 billion 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 finalizes 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 finalizes 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 made consistent with the rules in place as of January 1, 2018. The impacts are expected to cost \$260 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

After consideration of comments received on the proposed rule and for reasons we set forth previously and in the proposed rule, we are finalizing the three fee schedule adjustment methodologies we proposed without change. Specifically, we are finalizing the proposed revisions to § 414.210(g)(9) to adjust the fee schedule amounts for items and services furnished

in rural and noncontiguous non-CBAs by extending through December 31, 2020 the current fee schedule adjustment methodology which bases the fee schedule amounts on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts. We are also finalizing our proposal to continue fully adjusting the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in non-rural and contiguous non-CBAs in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). We are also finalizing the proposed addition of paragraph (g)(10) to § 414.210 to establish a methodology for adjusting fee schedule amounts for items and services furnished in former CBAs during temporary gaps in the DMEPOS CBP.

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 and maintain the current fee schedule adjustment methodologies. This alternative is estimated by rounding to the nearer 5 million dollars and to save \$1.14 billion 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 requested public comments on these alternatives.

Altogether, we proposed, and are finalizing 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.

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 will 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 will lessen the offset applied to the stationary oxygen equipment fee schedule amount, which will 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. Note that certain

beneficiaries will have increased cost sharing expenses depending on the type of equipment furnished.

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. Payment for Multi-Function Ventilators

i. Effects on Other Providers

We expect that the impact of classifying the multi-function ventilator item in the frequent and substantial servicing payment category and this final rule establishing payment rules for multi-function ventilators will overall result in a slight increase in payments to suppliers since the suppliers will 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 will retain ownership of the multi-function ventilator and can furnish the equipment for additional separate rental periods to other beneficiaries.

ii. Effects on the Medicare Program

We expect the final rule for multi-function ventilators to be a 5-year cost of \$15 million to the Medicare program as the payment method we are finalizing will 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 final rule will have an overall effect of increasing cost sharing by \$3 million for Medicare beneficiaries.

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 because the beneficiary cost share amount for the item would be the same amount as the total of that paid for each of the five items separately. 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 because the beneficiaries will end up paying the same amount as they would if they paid for five separate items together. 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.

e. Northern Mariana Islands in Future National Mail Order CBPs

Because the proposal we are finalizing will 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 50, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of these final rules.

TABLE 50: Accounting Statement: Classification of Estimated Transfers and Costs/Savings			
ESRD PPS and AKI			
Category	Transfers		
Annualized Monetized Transfers	\$160 million		
From Whom to Whom	Federal government to ESRD providers		
Category	Transfers		
Increased Beneficiary Co-insurance Payments	\$50 million		
From Whom to Whom	Beneficiaries to ESRD providers		
ESRD QIP for PY 2021			
Category	Transfers		
Annualized Monetized Transfers	-32 million		
From Whom to Whom	Federal government to ESRD providers.		
Category	Costs		
Annualized Monetized ESRD Provider Costs	181 million		
	The PY 2021 policy changes will result in an estimated \$12 million in savings.		
ESRD QIP for PY 2022			
Category	Transfers		
Annualized Monetized Transfers	-32 million		
From Whom to Whom	Federal government to ESRD providers		
Category	Costs		
Annualized Monetized ESRD Provider Costs	202 million		
	The PY 2022 policy changes will result in an estimated \$21 million increase.		
DME Provisions: Competitive Bidding Reforms Annualization Period 2019 to 2023			
Category	Transfer		
Annualized Monetized Transfer on Beneficiary Cost Sharing (in \$Millions)	Estimates	Year Dollar	Discount Rate
	\$2	2019	7%
	\$2	2019	3%
From Whom to Whom	Beneficiaries to Medicare providers		
Transfers			
Annualized Monetized Transfer Payments (in \$Millions)	Estimates	Year Dollar	Discount Rate
	\$0.6	2019	7%
	\$0.6	2019	3%

From Whom to Whom	Federal government to Medicare providers.		
DME Provisions: Transitional Fee Adjustments Annualization Period 2019 to 2020			
Category	Transfer		
Annualized Monetized Transfer on Beneficiary Cost Sharing (in \$Millions)	Estimates	Year Dollar	Discount Rate
	\$506	2019	7%
	\$516	2019	3%
From Whom to Whom	Beneficiaries to Medicare providers		
Transfers			
Annualized Monetized Transfer Payments (in \$Millions)	Estimates	Year Dollar	Discount Rate
	\$128	2019	7%
	\$130	2019	3%
From Whom to Whom	Federal government to Medicare providers.		
DME Provisions: Multi-function Ventilator Annualization Period 2019 to 2023			
Category	Transfer		
Annualized Monetized Transfer on Beneficiary Cost Sharing (in \$Millions)	Estimates	Year Dollar	Discount Rate
	\$3	2019	7%
	\$3	2019	3%
From Whom to Whom	Beneficiaries to Medicare providers		
Transfers			
Annualized Monetized Transfer Payments (in \$Millions)	Estimates	Year Dollar	Discount Rate
	\$0.6	2019	7%
	\$0.6	2019	3%
From Whom to Whom	Federal government to Medicare providers.		

In accordance with the provisions of Executive Order 12866, these final rules were reviewed by the Office of Management and Budget.

XVI. 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 42. Using the definitions in this ownership category, we consider 485 facilities that are independent and 327 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 finalized 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 1.8 percent increase in payments for CY 2019. An independent facility (as defined by ownership type) is also estimated to receive a 1.9 percent increase in payments for CY 2019.

For AKI dialysis, we are unable to estimate whether patients will 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 the PY 2021 ESRD QIP, we estimate that of the 3,240 ESRD facilities expected to receive a payment reduction in the PY 2021 ESRD QIP, 490 are ESRD small entity facilities. We present these findings in Table 43 (“Estimated Distribution of PY 2021 ESRD QIP Payment Reductions”) and Table 45 (“Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2021”). We estimate that the payment reductions will average approximately \$10,822.43 per facility across the 3,240 facilities receiving a payment reduction, and \$13,055.63 for each small entity facility. We also estimate that there are 804 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities will decrease 0.75 percent in PY 2021.

For the PY 2022 ESRD QIP, we estimate that of the 2,937 ESRD facilities expected to receive a payment reduction in the PY 2022 ESRD QIP, 488 are ESRD small entity facilities. We present these findings in Table 46 (“Estimated Distribution of PY 2022 ESRD QIP Payment Reductions”) and Table 48 (“Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2022”). We estimate that the payment reductions will average approximately \$10,767.50 per facility across the 2,937 facilities receiving a payment reduction, and \$12,929.28 for each small entity facility. We also estimate that there are 804 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities will decrease 0.37 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. For Section V of this final rule, 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 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 for the lead item. Therefore, we believe that this final rule will have a positive economic impact on bidding suppliers. As discussed in section VI of this final rule, this rule will 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 only sections V and VI of the final rule will 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.

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 604 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 final rule will 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. With regard to the DME provisions 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 provisions of the rule will have a significant impact on operations of a substantial number of small rural hospitals. As a result, this final rule is not estimated to have a significant impact on small rural hospitals.

Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

We solicited comment on the RFA analysis provided. We received 1 comment on this section. The comment and our response on our detailed economic analysis are set forth below.

Comment: One commenter said that although CMS estimated that the proposed rule would create significant costs for Medicare beneficiaries via cost sharing, the commenter believed that the increased access to quality DME and supplier/brand name choice is a beneficial trade-off. The commenter said that the true impact of this forecasted cost-sharing is unclear due to the widespread existence of secondary insurance, and that for beneficiaries who are dually eligible for both Medicare and Medicaid, Medicaid will typically pay the cost sharing, offsetting this total amount. The commenter also said that many beneficiaries who do not qualify for Medicaid, but cannot afford secondary insurance, do not end up paying for DME cost sharing out of pocket, and that it is common practice for suppliers to write off co-payments when beneficiaries cannot afford to pay after the supplier has made reasonable attempts to collect the balance. The commenter encouraged CMS to monitor how this cost increase impacts beneficiaries, but they believed the increase in access, quality, and choice will offset the legitimate concerns of increased beneficiary cost-sharing.

Response: While we appreciate the support for our proposal, we intend to carefully monitor of the impact of the final rule on access to DME and the quality of items and services furnished in areas that are currently CBAs and areas that are currently non-CBAs.

XVII. 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 final 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.

XVIII. 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 final rules under the threshold criteria of Executive Order 13132 on Federalism, and have determined that it will have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments. It is estimated that these policies contained in section VI of this final rule will add

\$30 million dollars of additional expense to state governments because of the added cost sharing expense for Medicare and Medicaid dual eligible beneficiaries.

XIX. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations “to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” The Department believes that this final rule is a significant regulatory action as defined by Executive Order 12866, which imposes costs, and therefore, is considered a regulatory action under Executive Order 13771. The estimated impact will be \$0.182875 million in costs in 2019, \$12 million in savings in 2021, and \$9 million in cost in 2022, and thereafter. Annualizing these costs and cost savings in perpetuity and discounting at 7 percent back to 2016, we estimate that this rule will generate \$5.45 million in annualized net costs for Executive Order 13771 accounting purposes.

XX. Congressional Review Act

These final 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.

XXI. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rules will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet 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-](http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-)
[Statistics-Data-and-Systems/Files-for-](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 amends 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: 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 (v) 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)(vi) 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, a measure (or measures) of patient satisfaction.

(4) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula).

(5) 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 0 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period falls below the achievement threshold specified for that measure.

(iii) 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.

(iv) CMS will award 0 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period is below the improvement threshold specified for that measure.

(v) 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.

(vi) 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 its 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 (effective January 1, 2020)--

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 product" in alphabetical order; and

b. By revising paragraphs (b) and (c).

The addition and revisions read as follows:

§ 413.234 Drug designation process.

(a) * * *

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product 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, 2020, 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 Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

* * * * *

(b) *Drug designation process.* New renal dialysis drugs or biological products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological product is added to an existing ESRD PPS functional category.

(ii) The new renal dialysis drug or biological product 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 product 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 product 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 product is used to treat or manage;

(ii) The new renal dialysis drug or biological product 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 product 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 product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of Average Sales Price (ASP), except that for calcimimetics it is based on the pricing methodologies under section 1847A of the Social Security Act. 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 is based on the drug manufacturer's invoice.

(1) A new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment 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 product 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 product 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)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

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 no longer applies.

* * * * *

(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 (f), 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) of this section, 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) and (f), 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), 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);
- f. By adding new paragraphs (e) and (f).
- g. In newly redesignated paragraph (g)(1)(i), by removing the reference “paragraph (e)(2)” and adding in its place the reference “paragraph (g)(2)”;
- and
- h. In newly redesignated paragraph (g)(2)(ii), by removing the reference “paragraph (e)(2)(i)” and adding in its place the reference “paragraph (g)(2)(i)”.

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--

- a. By revising paragraphs (b)(1) and (2);
- b. By revising paragraph (c);
- c. By removing paragraph (d); and
- d. By redesignating paragraphs (e) through (h) as paragraphs (d) through (g),

respectively;

e. In newly redesignated paragraph (e)(2) by removing the reference “paragraph (f)(1)” and adding in its place the reference “(e)(1)”; and

f. In newly redesignated paragraph (g)(2)(i)(D) by removing the reference “paragraph (h)(3)” and adding in its place the reference “ paragraph (g)(3)”.

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.

* * * * *

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 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, 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: October 26, 2018.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 29, 2018.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.