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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413 and 414

[CMS-1713-F]

RIN 0938-AT70

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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

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) 2020. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This rule also updates requirements for the ESRD Quality Incentive Program (QIP). In addition, this rule establishes a methodology for calculating fee schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services, and a methodology for making adjustments to the fee schedule amounts established using supplier or commercial prices if such prices decrease within 5 years of establishing the initial fee schedule amounts. This rule also revises existing regulations related

to the DMEPOS competitive bidding program. This rule also streamlines the requirements for ordering DMEPOS items, and develops a new list of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements. Finally, this rule summarizes responses to requests for information on data collection resulting from the ESRD PPS technical expert panel, changing the basis for the ESRD PPS wage index, and new requirements for the competitive bidding of diabetic testing strips.

DATES: These regulations 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.

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

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

Julia Howard, (410) 786-8645, for issues related to DMEPOS CBP Amendments

Jennifer Phillips, (410) 786-1023; Olufemi Shodeke, (410) 786-1649; and

Maria Ciccanti, (410) 786-3107, for issues related to the DMEPOS written order, face-to-face encounter, and prior authorization requirements.

SUPPLEMENTARY INFORMATION:

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

This final rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, the DMEPOS Competitive Bidding Program (CBP), and the

regulations governing DMEPOS orders, face-to-face encounters, and prior authorization.

In future rulemaking years, the DMEPOS provisions will be in a separate rule from the ESRD PPS, AKI and ESRD QIP provisions.

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) (Pub. L. 110–275). 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 2020.

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 2020.

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

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters 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 final rule finalizes several updates to the ESRD QIP.

4. DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule establishes a gap-filling methodology for the pricing of new DMEPOS items and services in accordance with sections 1834(a), (h), (i) and 1833(o) of the Act for DME, prosthetic devices, orthotics, prosthetics, surgical dressings, and custom molded shoes, extra-depth shoes, and inserts, and section 1842(b) for parental and enteral nutrients (PEN) and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

This rule finalizes a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent within 5 years of establishing the initial fee

schedule amounts.

5. Conditions of Payment to be Applied to Certain DMEPOS Items

This rule will streamline the requirements for ordering DMEPOS items. It will also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2020*: The final CY 2020 ESRD PPS base rate is $239.33. This amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.7 percent), and application of the wage index budget-neutrality adjustment factor (1.000244), equaling $239.33 ($235.27 x 1.017 x 1.000244 = $239.33).

- *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 2020, 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 2020 using CY 2018 claims data. Based on the use of the latest available data, the final FDL amount for pediatric beneficiaries will decrease from $57.14 to $41.04, and the MAP amount will decrease from $35.18 to $32.32, as compared to CY 2019

values. For adult beneficiaries, the final FDL amount will decrease from $65.11 to $48.33, and the MAP amount will decrease from $38.51 to $35.78. The 1.0 percent target for outlier payments was not achieved in CY 2018. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent. We believe using CY 2018 claims data to update the outlier MAP and FDL amounts for CY 2020 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1.0 percent outlier percentage.

- *Eligibility criteria for the transitional drug add-on payment adjustment (TDAPA)*: We are finalizing revisions to the drug designation process regulation at 42 CFR 413.234 for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Specifically, we are excluding drugs approved by the Food and Drug Administration (FDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8— from being eligible for the transitional drug add-on payment adjustment (TDAPA), effective January 1, 2020.

- *Modification of the basis of payment for the TDAPA for calcimimetics*: We will continue to pay the TDAPA for calcimimetics for a third year in CY 2020 in order to collect sufficient claims data for rate setting analysis, but we are finalizing a reduction to the basis of payment for the TDAPA for calcimimetics for CY 2020 from the average sales price plus 6 percent (ASP+6) methodology to 100 percent of ASP.

- *Average sales price (ASP) conditional policy for application of the TDAPA*:

Effective January 1, 2020, the basis of payment for the TDAPA for all new renal dialysis drugs and biological products is ASP+0, but if ASP data is not available, then we use Wholesale Acquisition Cost (WAC) +0, and if WAC is not available, then we use invoice pricing. We are finalizing a policy to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for that product. We will no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. We are also finalizing a policy to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive the latest full calendar quarter of ASP data for the product, beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

- *New and innovative renal dialysis equipment and supplies*: We are finalizing our proposal to establish a transitional add-on payment adjustment to support ESRD facilities in the uptake of certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. We will pay this adjustment, which we are calling the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), for equipment and supplies that: (1) have been designated by CMS as a renal dialysis service, (2) are new, meaning granted marketing authorization by FDA on or after January 1, 2020, (3) are commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) have a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official

Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) are innovative, meaning they meet the substantial clinical improvement (SCI) criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at 42 CFR 412.87(b)(1) and related guidance, and (6) are not capital-related assets. Specifically, the equipment or supply must represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year.

We are finalizing that the TPNIES will be based on 65 percent of the price established by the Medicare Administrative Contractors (MACs), using the information from the invoice and other relevant sources of information. We will pay the TPNIES for 2-calendar years, after which the equipment or supply will qualify as an outlier service and no change to the ESRD PPS base rate will be made.

- *Erythropoiesis-stimulating agent (ESA) monitoring policy (EMP*): We are discontinuing the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS.

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

We are updating the AKI payment rate for CY 2020. The final CY 2020 payment rate is $239.33, which is the same as the base rate finalized under the ESRD PPS for CY 2020.

3. ESRD QIP

We are finalizing several new requirements for the ESRD QIP beginning with payment

year (PY) 2022, including an updated scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure to allow new facilities and facilities that are eligible to report data on the measure for less than 12 months to be able to receive a score on that measure, and the conversion of the STrR clinical measure (National Quality Forum [NQF] #2979) to a reporting measure while we continue to examine concerns raised by stakeholders regarding the measure's validity. We are not finalizing our proposal to revise the scoring methodology for the MedRec reporting measure and will continue to score that measure using the methodology we adopted in the CY 2019 ESRD PPS final rule.

We are also finalizing the performance and baseline periods for the PY 2023 ESRD QIP and that, beginning with the PY 2024 payment year, we will automatically adopt performance and baseline periods that are advanced 1 year from those specified for the previous payment year.

Finally, we are updating our regulation text so that it better informs the public of the Program's requirements.

4. DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This rule finalizes a specific methodology for calculating fee schedule amounts for new DMEPOS items. The fiscal impact of establishing payment amounts for new items based on our proposal cannot be estimated as these new items are not identified and would vary in uniqueness and costs. However, there is some inherent risk that the methodology could result in fee schedule amounts for new items that greatly exceed the costs of furnishing the items.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

In cases where fee schedule amounts for new DMEPOS items and services are gap-filled

using supplier or commercial prices, these prices may decrease over time. In cases where such prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts, this rule finalizes a one-time adjustment to the gap-filled fee schedule amounts. We will not make these price adjustments in cases where prices increase.

5. Conditions of Payment to be Applied to Certain DMEPOS Items

This rule will streamline the requirements for ordering DMEPOS items. It will also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

C. Summary of Costs and Benefits

In section X 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 X of this final rule displays the estimated change in payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the CY 2020 changes is projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 2.1 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 2020 compared to CY 2019. This reflects a $220 million increase from the payment rate update, a $50 million increase due to the updates to the outlier threshold amounts, and a $60 million decrease due to the change in the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent. These figures do not reflect

estimated increases or decreases in expenditures based on the refinement to the TDAPA eligibility criteria, conditioning the TDAPA on the availability of ASP data, or providing the TPNIES. The fiscal impact of these policies cannot be determined because the new renal dialysis drugs and biological products eligible for the TDAPA and new renal dialysis equipment and supplies eligible for the TPNIES are not yet identified and would vary in uniqueness and costs. 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 2020, which translates to approximately $40 million.

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

The impact chart in section X of this final rule displays the estimated change in payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the CY 2020 changes is projected to be a 1.7 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.6 percent increase in payments compared with freestanding facilities with an estimated 1.7 percent increase.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the final CY 2020 ESRD PPS base rate will increase by less than $1 million in CY 2020 compared to CY 2019.

3. Impacts of the Final ESRD QIP Requirements

We estimate that the overall economic impact of the PY 2022 ESRD QIP will be approximately $229 million as a result of the policies we have previously finalized and the proposals we are finalizing in this final rule. The $229 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate will be

approximately $211 million. We also estimate that the overall economic impact of the PY 2023 ESRD QIP will be approximately $223 million as a result of the policies we have previously finalized and are finalizing beginning with PY 2022. The $229 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate will be approximately $211 million.

4. Impacts of the Final DMEPOS Fee Schedule Payment Rules

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

This final rule establishes a specific methodology for calculating fee schedule amounts for new DMEPOS items. The fiscal impact of establishing payment amounts for new items based on this methodology cannot be estimated as the new DMEPOS items are not identified and would vary in uniqueness and costs. However, there is some inherent risk that the final methodology could result in fee schedule amounts for new items that greatly exceed the costs of furnishing the items.

b. Adjusting Gap-Filled Payment Amounts for DMEPOS Items and Services Using Supplier or Commercial Prices

We are finalizing a one-time adjustment to the gap-filled fee schedule amounts in cases where fee schedule amounts for new DMEPOS items and services are gap-filled using supplier or commercial prices, and these prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts. The one-time adjustment should generate savings although it will probably be a small offset to the potential increase in costs of establishing fee schedule amounts based on supplier invoices or prices from commercial payers. The fiscal impact for this provision is therefore considered negligible.

5. Conditions of Payment to be Applied to Certain DMEPOS Items

This rule streamlines the requirements for ordering DMEPOS items, and identifies the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

II. Calendar Year (CY) 2020 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 § 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 (IV) 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). In the CY 2019 ESRD PPS final rule (83 FR 56929 through 56949), we finalized a policy to make the TDAPA available for all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories, effective January 1, 2020.

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 14, 2018, 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, 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

56922 through 57073) (hereinafter referred to as the CY 2019 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2019, the wage index, and the outlier policy, and we finalized revisions to the drug designation process and the low-volume payment adjustment. For further detailed information regarding these updates, see 83 FR 56922.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2020 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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 38330 through 38421), hereinafter referred to as the "CY 2020 ESRD PPS proposed rule," was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that proposed rule, for the ESRD PPS, we proposed to make a number of annual updates for CY 2020, including updates to the ESRD PPS base rate, wage index, and outlier policy. We also proposed revisions to the drug designation process regulation at 42 CFR 413.234 for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, a change in the basis of payment for the TDAPA for calcimimetics, and an average sales price (ASP) conditional policy for the application of the TDAPA. In addition, we proposed to establish a transitional add-on payment adjustment for certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. We also proposed to discontinue the application

of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS.

We received approximately 92 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 2020 ESRD PPS.

1. Eligibility Criteria for the Transitional Drug Add-on Payment Adjustment (TDAPA)

a. Background

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. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and IV 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 FDA. Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition

for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV 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.

In the CY 2016 ESRD PPS final rule, we also established in § 413.234(b)(2) that, if the new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV 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 IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA described in § 413.234(c). Then, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

After the publication of the CY 2016 ESRD PPS final rule, we continued to hear from the dialysis industry and other stakeholders with suggestions for improving the drug designation process. Therefore, in CY 2019 ESRD PPS rulemaking, we revisited the drug designation

process to consider their concerns and we proposed policies that would mitigate these issues.

In the CY 2019 ESRD PPS final rule (83 FR 56929 through 56949), we finalized several provisions related to the drug designation process and the TDAPA under § 413.234, with an effective date of January 1, 2020. In particular, we finalized changes to the drug designation process regulation to: (1) reflect that the process applies for all new renal dialysis drugs and biological products; (2) establish a definition for "new renal dialysis drug or biological product"; (3) expand the eligibility criteria for the TDAPA; (4) change the TDAPA's basis of payment; and (5) extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. We discuss these changes in detail in the next several paragraphs.

First, we revised the drug designation process regulation at § 413.234 to reflect that the drug designation process applies for all new renal dialysis drugs and biological products that are approved by FDA, regardless of the form or route of administration, that are used to treat or manage a condition associated with ESRD. In the CY 2019 ESRD PPS proposed rule (83 FR 34309 through 34312), we described the prior rulemakings in which 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. We explained that the drug designation process is dependent upon the ESRD PPS functional categories we developed, and is consistent with the policy we have followed since the inception of the ESRD PPS.

However, we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34311 through 34312) that, because section 217(c)(2) of PAMA only required the Secretary to establish a process for including new injectable and IV 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 explained that we did not codify our full policy in the CY 2016 ESRD PPS final rule 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). Commenters were generally supportive of the proposal, and we finalized the changes to codify our drug designation policy with regard to all drugs.

Second, as part of our updates to the drug designation process regulation in the CY 2019 ESRD PPS final rule (83 FR 56929 through 56932), we replaced the definition of "new injectable or intravenous product" with a definition for "new renal dialysis drug or biological product." Under the final definition, effective January 1, 2020, a "new renal dialysis drug or biological product" is 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 [FDA] on or after January 1, 2020, under section 505 of the [FD&C 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."

Third, we expanded the eligibility criteria for the TDAPA to include all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories, in the CY 2019 ESRD PPS final rule (83 FR 56942 through 56843). In the CY 2019 ESRD PPS proposed rule (83 FR 34312 through 34314), we discussed a number of reasons why we were reconsidering our previous policy to limit the TDAPA to products for which there is not an ESRD PPS functional category. We described the concerns that commenters had raised during

the CY 2016 ESRD PPS rulemaking regarding the eligibility criteria for the TDAPA, including concerns about inadequate payment for renal dialysis services and hindrance of high-value innovation, and noted that these are important issues that we contemplate while determining appropriate payment policies. We discussed that when new drugs and biological products 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. We recognized that 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, we stated that practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes.

We explained in the CY 2019 ESRD PPS proposed rule that this uptake period would be best supported by the TDAPA pathway because it would help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We stated that the TDAPA could provide flexibility and target 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. We further explained 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. Thus, we proposed to revise § 413.234(c) to reflect that the TDAPA would apply for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category, and, for those products that fall within an existing functional category, the payment would apply for only 2 years and there would be no subsequent modification to the ESRD PPS base rate (83 FR 34314). At the end of the 2 years, the product would be eligible for outlier payment

unless it is a renal dialysis composite rate drug or biological product.

As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56934 through 56943), we received a variety of feedback from stakeholders on this proposal. Some commenters recommended delaying the expansion of the TDAPA and some urged CMS to consider different policy proposals. Some commenters were supportive of revising the drug designation process regulation to allow more drugs to be eligible for the TDAPA, while others expressed that the process needs to be further evaluated before any expansion. The Medicare Payment Advisory Commission (MedPAC) recommended that we not finalize the policy because it did not require that a new drug be more effective than current treatment and could undermine competition with existing drugs; or, if we do move forward with the policy, that we narrow eligibility to new drugs that fall into an existing ESRD PPS functional category only if they substantially improve beneficiaries' outcomes.

Other commenters had similar concerns and recommended that we require that the TDAPA apply for new renal dialysis drugs and biological products that have clinical superiority over the existing products in the existing functional categories, and they provided suggestions on clinical value criteria. In addition, some commenters believed that the TDAPA should not apply to generic drugs and biosimilar biological products. Commenters asserted that generic drugs and biosimilar biological products seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Commenters further believed that these types of drugs and biological products have no clinically meaningful differences and that they should be treated equally in payment and coverage policies. We also received several comments on our proposal to apply the TDAPA for a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate for 2 years, and to not modify the ESRD PPS

base rate following payment of the TDAPA (83 FR 56934 through 56943).

After considering the public comments, in the CY 2019 ESRD PPS final rule, we finalized the expansion of the eligibility criteria for the TDAPA to reflect the proposed policy (83 FR 56943). We explained that there are 2 purposes of providing the TDAPA. For renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the purpose of the TDAPA is to help ESRD facilities to incorporate new drug and biological products and make appropriate changes in their businesses to adopt such products; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories. For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category and that are not considered to be reflected in the ESRD PPS base rate, the purpose of the TDAPA is to be a pathway toward a potential base rate modification (83 FR 56935).

In response to commenters that recommended clinical superiority of new renal dialysis drugs and biological products, we explained in the CY 2019 ESRD PPS final rule (83 FR 56938) that we believed allowing all new drugs and biological products to be eligible for the TDAPA would enable new drugs and biological products to compete with other drugs and biological products in the market, which could mean lower prices for all such products. We also noted our belief that categorically limiting or excluding any group of drugs from the TDAPA would reduce the competitiveness because there would be less incentive for manufacturers to develop lower-priced drugs, such as generic drugs and biosimilar biological products, to be able to compete with higher priced drugs during the TDAPA period. In addition, we noted the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic pre-disposition and comorbidities. We stated

that innovation can provide options for those patients who do not respond to a certain preferred treatment regimen the same way the majority of patients respond.

In response to commenters who recommended that we not apply the TDAPA to generic drugs and biosimilar biological products, we explained in the CY 2019 ESRD PPS final rule (83 FR 56938) that the purpose of this policy is to foster a competitive marketplace in which all drugs within a functional category would compete for market share. We stated that we believed including generic drugs and biosimilar biological products under the TDAPA expansion would mitigate or discourage high launch prices. We further explained that we believed including these products would foster innovation of drugs within the current functional categories. We also noted that we believed including these products would give a financial boost to support their utilization, and ultimately lower overall drug costs since these products generally have lower prices. Because of this, we stated that we believed that generic drugs and biosimilar biological products would provide cost-based competition for new higher priced drugs during the TDAPA period and also afterward when they are bundled into the ESRD PPS.

In response to ESRD facilities that expressed concern regarding operational difficulties and patient access issues experienced for current drugs paid for using the TDAPA, we elected to make all of the changes to the drug designation process under § 413.234 and the expansion of the TDAPA eligibility effective January 1, 2020, as opposed to January 1, 2019, to address as many of those concerns as possible (83 FR 56937). We explained in the CY 2019 ESRD PPS final rule that the additional year would provide us with the opportunity to address issues such as transitioning payment from Part D to Part B, coordinating issues involving Medicaid and new Medicare Advantage policies, and working with the current HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new drugs and biological products. We also

indicated that the additional year would allow more time for ESRD facility and beneficiary education about this new policy.

In addition, with regard to the HCPCS process, we explained the additional year would help us operationally in working with the HCPCS workgroup that manages the HCPCS process as it applies to the ESRD PPS to accommodate the initial influx of new renal dialysis drugs and biological products. We explained that in collaboration with the HCPCS workgroup we would make the determination of whether a drug or biological product is a renal dialysis service. We would 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 (83 FR 56937 through 56938).

With regard to our proposal to not modify the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing ESRD PPS functional categories, we explained that we believe the intent of the TDAPA for these products is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new product. We further explained that we did not believe it would 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 such would be in conflict with the fundamental principles of a PPS.

We also explained that the 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 supporting high-value innovation and allowing facilities to adjust or factor in new drugs through a short-term transitional payment.

We stated in the CY 2019 ESRD PPS final rule (83 FR 56940) that 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 the 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, we continued the existing policy that application of the 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.

Fourth, in the CY 2019 ESRD PPS final rule, we changed the TDAPA's basis of payment (83 FR 34314 through 34316). We explained that if we adopted the proposals to expand the TDAPA eligibility criteria using the current basis of payment for the TDAPA—the pricing methodologies available under section 1847A of the Act—Medicare expenditures would increase, which would result in increases of cost sharing for ESRD beneficiaries, since we had not previously provided the TDAPA for all new renal dialysis drugs and biological products. We also discussed other reasons why we believed it may not be appropriate to base the TDAPA strictly on section 1847A of the Act methodologies (83 FR 34315).

Therefore, we proposed to base the TDAPA on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6). For circumstances when ASP data is not available, we proposed that the TDAPA would be based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the TDAPA would be based on the drug manufacturer's invoice.

In the CY 2019 ESRD PPS final rule (83 FR 56943 through 56948), we discussed several comments received on this proposal. MedPAC supported the proposal to use ASP+0, stating that

the ESRD PPS accounts for storage and administration costs and that ESRD facilities do not have acquisition price variation issues when compared to physicians. Conversely, industry stakeholders recommended the basis of payment remain at ASP+6 since they believe it assists with the administrative costs of packaging, handling, and staff. Commenters also recommended that CMS consider the impact of bad debt recovery and sequestration on payment when determining the basis of payment.

After considering public comments, in the CY 2019 ESRD PPS final rule (83 FR 56948), we finalized the policy as proposed, with one revision to change the effective date to CY 2020, and another revision to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We explained that we believed ASP+0 is reasonable 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 explained that we believed 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 (83 FR 56946).

Fifth and finally, in the CY 2019 ESRD PPS final rule (83 FR 56948 through 56949), we finalized a 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 § 413.234(a) is considered to be a composite rate drug or biological product and falls within an existing ESRD PPS functional category, it will be eligible for the TDAPA.

We explained that we believed by allowing all new renal dialysis drugs and biological products to be eligible for the TDAPA, we would 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 further explained that we believed that new renal dialysis composite rate drugs and biological products could benefit from this policy as well. Additionally, we explained that 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 noted that we had not proposed to change the outlier policy and therefore these products will not be eligible for an outlier payment after the TDAPA period.

b. Basis for Refinement of the TDAPA Eligibility Criteria

In the CY 2020 ESRD PPS proposed rule (84 FR 38337 through 38339), we explained that based on feedback received during and after the CY 2019 ESRD PPS rulemaking, we were proposing to make further refinements to the TDAPA eligibility criteria. As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56935) and in section II.B.1.a of this final rule, we received many comments from all sectors of the dialysis industry and other stakeholders on our proposal in the CY 2019 ESRD PPS rulemaking to expand the TDAPA eligibility to all new renal dialysis drugs and biological products, and each had their view on the direction the policy needed to go to support innovation. We noted in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that 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 an ESRD PPS functional category should be eligible for a payment adjustment when they are new

to the market. However, we noted that commenters also had specific policy recommendations for each element of the drug designation process, including which drugs should qualify for the TDAPA.

We also noted in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that in the CY 2019 ESRD PPS final rule (83 FR 56938) some commenters recommended that CMS not apply the TDAPA to generic drugs or to biosimilar biological products. These commenters explained that they believe the rationale for the TDAPA is to allow the community and CMS to better understand the appropriate utilization of new products and their pricing. We also noted that commenters asserted that generic drugs and biosimilar biological products seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Thus, they expressed that the additional time for uptake is unnecessary for these drugs and biological products.

In addition, we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that a drug manufacturer had commented on the CY 2019 TDAPA proposal (83 FR 56938) that a generic drug is not innovative because it must have the same active ingredient, strength, dosage form, and route of administration as the innovator drug it references in its abbreviated new drug application (ANDA). The drug manufacturer further stated that a biosimilar biological product is not innovative because it is required under the Public Health Service Act (the PHS Act) to be highly similar and have no clinically meaningful differences to the reference product and cannot be licensed for a condition of use that has not been previously approved for the reference product or for a dosage form, strength, or route of administration that differs from that of the reference product. We noted that the commenter stated that because they have no clinically meaningful differences, biosimilar biological products and reference products should be treated equally in

payment and coverage policies; a biosimilar biological product should not be eligible for the TDAPA when its reference product would not qualify for the payment.

We further explained in the CY 2020 ESRD PPS proposed rule (84 FR 38338), that some commenters on the CY 2019 TDAPA proposal recommended that CMS require that the new renal dialysis drug or biological product have a clinical superiority over existing drugs in the ESRD PPS bundled payment in order to be eligible for the TDAPA, and provided suggestions on clinical value criteria. We stated that a dialysis facility organization 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. We noted that a drug manufacturer recommended that CMS consider when FDA may re-profile a drug and that the commenter further explained that re-profiling a drug may occur when its utility and efficacy are further elucidated or expanded once on-market. We also noted that 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.

In the CY 2020 ESRD PPS proposed rule (84 FR 38338) we discussed MedPAC's comment from the CY 2019 ESRD PPS final rule (83 FR 56936). MedPAC had recommended that CMS not proceed with its proposal to apply the TDAPA policy to new renal dialysis drugs that fit into an existing functional category for several reasons. For example, MedPAC stated that 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 PPS bundle. MedPAC also asserted that applying the TDAPA to new dialysis drugs that fit into an existing functional category undermines competition with existing drugs included in the PPS payment bundle since

the TDAPA would effectively unbundle all new dialysis drugs, removing all cost constraints during the TDAPA period and encouraging the establishment of high launch prices.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that since publishing the CY 2019 ESRD PPS final rule, we have continued to hear concerns about expanding the TDAPA policy from numerous stakeholders, including ESRD facilities and their professional associations, beneficiaries and their related associations, drug manufacturers, and beneficiary groups.

We also stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338), that our data contractor held a Technical Expert Panel (TEP) in December 2018, and gathered input regarding the expanded TDAPA policy at that time. More information about the TEP is discussed in section VIII.A of the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), and in section VIII.A of this final rule. We noted that some ESRD facility associations participating in the TEP generally expressed concern that the TDAPA policy, as finalized in the CY 2019 ESRD PPS final rule, would inappropriately direct Medicare dollars to drugs and biological products that may be new to the market but not new with regard to certain characteristics of the drug itself. For example, commenters noted that section 505 of the FD&C Act is broad and includes FDA approval of a new drug application (NDA), which is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the U.S.[1] We explained that section 505 of the FD&C Act, which includes sections 505(b)(1) and (b)(2) and 505(j) for generic drugs, includes FDA approval of NDAs for drugs that have a new dosage form, a reformulation, or a re-engineering of an existing product and that some of these types of drugs are referred to in the pharmaceutical industry as line extensions, follow-on

1 FDA. New Drug Application (NDA). Available at: https://www.fda.gov/drugs/types-applications/new-drug-application-nda

products, or me-too drugs.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that due to the feedback received following publication of the CY 2019 ESRD PPS final rule, we had continued to analyze certain aspects of the policies finalized in the CY 2019 ESRD PPS final rule and therefore we were revisiting those issues as part of that rule. Specifically, since ESRD facilities and other dialysis stakeholders have expressed concern about the broad nature of including all new renal dialysis drugs and biological products as eligible for the TDAPA, we were reconsidering whether all new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category should be eligible for the TDAPA.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38338) that in the CY 2019 ESRD PPS final rule (83 FR 56932) we finalized that effective January 1, 2020, a new renal dialysis drug or biological product is defined in § 413.234 as "[a]n 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 FDA on or after January 1, 2020, under section 505 of the [FD&C Act] or section 351 of the [PHS 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." We noted that while there are several parts of this definition, in the proposed rule we focused on the requirement that the product be approved by FDA "under section 505 of the [FD&C Act] or section 351 of the [PHS Act]." Specifically, we proposed that certain new renal dialysis drugs approved by FDA under those authorities would not be eligible for the TDAPA under § 413.234(c)(1).

We explained in the CY 2020 ESRD PPS proposed rule (84 FR 38338 through 38339)

that section 505 of the FD&C Act and section 351 of the PHS Act provide the authority to FDA for approving drugs and biological products, respectively, and provide several pathways for drug manufacturers to submit NDAs and biologics license applications (BLAs). We noted that we have consulted with FDA and studied the different categories of NDAs and the different biological product pathways to consider whether the full breadth of these authorities aligned with our goals for the TDAPA policy under the ESRD PPS. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56935), the purpose of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category is to support innovation and help ESRD facilities to incorporate new products and make appropriate changes in their businesses to adopt such products; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories.

We explained that FDA approves certain new drugs under section 505(c) of the FD&C Act, which includes NDAs submitted pursuant to section 505(b)(1) or 505(b)(2) of the FD&C Act. We further explained that section 505(b)(1) of the FD&C Act is a pathway for "stand-alone" applications and is used for drugs that have been discovered and developed with studies conducted by or for the applicant or for which the applicant has a right of reference, and are sometimes for new molecular entities and new chemical entities that have not been previously approved in the U.S.

We also explained that section 505(b)(2) of the FD&C Act is another pathway for NDAs, where at least some of the information for an approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) application may rely on FDA's finding of safety and/or effectiveness for a listed drug (an approved drug product) or published literature provided that such reliance is scientifically

justified and the 505(b)(2) applicant complies with the applicable statutory and regulatory requirements, including patent certification if appropriate. (See section 505(b)(2) of the FD&C Act and 21 CFR 314.54.) NDAs submitted pursuant to section 505(b)(1) or 505(b)(2) of the FD&C Act are divided into categories by FDA.

We explained in the CY 2020 ESRD PPS proposed rule (84 FR 38339) that the Office of Pharmaceutical Quality in FDA's Center for Drug Evaluation and Research (CDER) has an NDA categorizing system that utilizes NDA Classification Codes. As explained in FDA/CDER Manual of Policies and Procedures (MAPP) 5018.2, "NDA Classification Codes", the codes evolved from both a management and a regulatory need to identify and group product applications based on certain characteristics, including their relationships to products already approved or marketed in the U.S. FDA tentatively assigns an NDA Classification Code (that is, Type 1 NDA through Type 10 NDA) by the filing date for an NDA and reassesses the code at the time of approval. The reassessment is based upon relationships of the drug product seeking approval to products already approved or marketed in the U.S. at the time of approval. FDA may also reassess the code after approval. We stated that the NDA Classification Codes are not necessarily indicative of the extent of innovation or therapeutic value that a particular drug represents. More information regarding the NDA Classification Codes is available in FDA/CDER MAPP 5018.2 on FDA website at: https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm470773.pdf and summarized in Table 1.

TABLE 1: NDA Classification Codes

Classification	Meaning
Type 1	New molecular entity

Classification	Meaning
Type 2	New active ingredient
Type 3	New dosage form
Type 4	New combination
Type 5	New formulation or other differences
Type 6	New indication or claim, same applicant [no longer used]
Type 7	Previously marketed but without an approved NDA
Type 8	Prescription to Over-the-Counter
Type 9	New indication or claim, drug not to be marketed under type 9 NDA after approval
Type 10	New indication or claim, drug to be marketed under type 10 NDA after approval
Type 1/4	Type 1, New molecular entity, and Type 4, New combination
Type 2/3	Type 2, New active ingredient, and Type 3, New dosage form
Type 2/4	Type 2, New active ingredient and Type 4, New combination
Type 3/4	Type 3, New Dosage Form, and Type 4, New combination

We further explained in the CY 2020 ESRD PPS proposed rule (84 FR 38339) that an ANDA is an application submitted by drug manufacturers and approved by FDA under section 505(j) of the FD&C Act for a "duplicate" [2] of a previously approved drug product. We noted that ANDAs are used for generic drugs and rely on FDA's finding that the previously approved drug product, that is, the reference listed drug, is safe and effective.

We stated that biological products are licensed by FDA under section 351 of the PHS Act. Section 351(a) of the PHS Act is the pathway for "stand-alone BLAs" that contain all

2 The term *duplicate* generally refers to a "drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as a listed drug," as a previously approved drug product. See 54 FR 28872 (July 10, 1989). An exception to this general rule is that FDA may approve ANDAs with certain changes from a listed drug regarding active ingredient, dosage form, strength, and route of administration if a "suitability petition" has been approved under section 505(j)(2)(C) of the FD&C Act.

information and data necessary to demonstrate that (among other things) the proposed biological product is safe, pure and potent. The 351(k) BLA pathway requires that the application contain information demonstrating that the biological product is biosimilar to or interchangeable with an FDA-licensed reference product. We noted that FDA does not assign classification codes for BLAs like it does for NDAs.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38339) that in addition to consulting with FDA, pharmaceutical statisticians within CMS have provided insight on the potential outcomes of providing payment incentives for promoting competition among drugs and biological products within the ESRD PPS functional categories. Specifically, we learned that certain unintended consequences could arise from providing payment incentives for drugs with innovative qualities (for example, new molecular entities) in the same way as drugs with non-innovative qualities (for example, generic drugs). For example, more attention might be diverted to the less costly duplication of drugs that are already available rather than those that may be more expensive to develop and bring to market. We noted that we believed this could cause an influx of non-innovative drugs to the dialysis space, potentially crowding out innovative drugs.

c. Proposed Refinement of the TDAPA Eligibility Criteria

In the CY 2020 ESRD PPS proposed rule (84 FR 38339 through 38340) we explained that we analyzed the information we gathered since publishing the CY 2019 ESRD PPS final rule and contemplated the primary goal of the TDAPA policy for new renal dialysis drugs and biological products that fall within ESRD PPS functional categories, which is to support innovation and encourage development of these products. We stated that we believed this is accomplished by providing an add-on payment adjustment to ESRD facilities during the uptake period for a new renal dialysis drug or biological product to help the facilities incorporate new

drugs and make appropriate changes in their businesses to adopt such drugs. We also noted that the TDAPA provides additional payment for costs associated with these changes.

We stated that in addition to supporting innovation, we were mindful of the increase in Medicare expenditures associated with the expanded TDAPA policy. We noted that the first year in which we paid the TDAPA, CY 2018, resulted in an estimated $1.2 billion increase in ESRD PPS expenditures for two calcimimetic drugs used by approximately 25 percent of the Medicare ESRD population. We recognized that the policy we finalized in the CY 2019 ESRD PPS final rule would mean that each new renal dialysis drug and biological product eligible for the TDAPA would result in an increase in Medicare expenditures. However, we noted that we were balancing an increase in Medicare expenditures with the rationale for fostering a competitive marketplace. We noted that in the CY 2019 ESRD PPS final rule (83 FR 56937), we stated our belief that by expanding the eligibility for TDAPA to all new drugs and biological products we would promote competition among drugs and biological products within the ESRD PPS functional categories, which could result in lower prices for all drugs.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38340) that in response to ESRD facility and other dialysis stakeholders' concerns raised during and after the CY 2019 ESRD PPS rulemaking, and after conducting a closer study of FDA's NDA process, we were reconsidering the eligibility criteria that we finalized effective January 1, 2020. Since there are not unlimited Medicare resources, we stated that we believed those resources should not be expended on additional payments to ESRD facilities for drugs and biological products that are not truly innovative, and that such additional payments may facilitate perverse incentives for facilities to choose new products simply for financial gain. We also noted that we believed that since we have the ability to be more selective, through FDA's NDA Classification Codes, with

the categories of renal dialysis drugs that would be eligible for the TDAPA for products in existing ESRD PPS functional categories, we can balance supporting innovation, incentivizing facilities with uptake of new and innovative renal dialysis products, and fostering competition for renal dialysis drugs and biological products that are new and innovative, rather than just new.

We acknowledged that the definition finalized in the CY 2016 ESRD PPS final rule (80 FR 69015 through 69027), which includes products "approved by [FDA] . . . under section 505 of the [FD&C Act] or section 351 of the [PHS Act]" has been part of the TDAPA eligibility criteria since the inception of the policy. We also acknowledged that this may be too expansive for purposes of determining eligibility for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category. For example, there may be new renal dialysis drugs approved by FDA under section 505 of the FD&C Act that may not be innovative.

We also acknowledged that while dialysis industry stakeholders recommended that we adopt significant clinical improvement standards for the TDAPA eligibility, we believed that unlike many Medicare beneficiaries, the Medicare ESRD beneficiary is significantly complex, with each patient having a unique and challenging profile for medical management of drugs and biological products. We stated that we believed that practitioners should have the opportunity to evaluate the appropriate use of a new drug or biological product and its effect on patient outcomes and interactions with other medications the patient is currently taking. We further noted that the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic pre-disposition and comorbidities. We stated that we believed that innovation of drugs and biological products can provide options for those patients who do not respond to a certain preferred treatment regimen

the same way the majority of patients respond.

Therefore, in the CY 2020 ESRD PPS proposed rule (84 FR 38341 through 38344) we discussed categories of drugs that we proposed to exclude from eligibility for the TDAPA and our proposed revisions to the drug designation process regulation in § 413.234 to reflect those categories.

We also proposed to rely on, as a proxy, the NDA Classification Code, as it exists as of November 4, 2015, which is part of FDA/CDER MAPP 5018.2 (84 FR 38340). The FDA/CDER MAPP 5018.2 is available at FDA website https://www.fda.gov/media/94381/download. We recognized that FDA's NDA Classification Codes do not necessarily reflect the extent of innovation or therapeutic advantage that a particular drug product represents. However, we stated that we believed FDA's NDA Classification Codes would provide an objective basis that we can use to distinguish innovative from non-innovative renal dialysis service drugs. We noted that we believed that distinguishing drugs would help us in our effort to support innovation by directing Medicare resources to renal dialysis drugs and biological products that are not reformulations or new dosage forms, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost.

We stated that the classification code assigned to an NDA generally describes FDA's classification of the relationship of the drug to drugs already marketed or approved in the U.S. We proposed that if FDA makes changes to the NDA Classification Codes in FDA/CDER MAPP 5018.2, we would assess FDA changes at the time they are publicly available and we would analyze those changes with regard to their implications for the TDAPA policy under the

ESRD PPS (84 FR 38340). We stated that we would plan to propose in the next rulemaking cycle, any necessary revisions to the exclusions set forth in proposed § 413.234(e). We solicited comment on the proposal to rely on, as a proxy, the NDA Classification Codes, as it exists as of November 4, 2015, which is part of the FDA/CDER MAPP 5018.2. We also solicited comments on the proposal that we would assess FDA changes to the NDA Classification Codes at the time they are publicly available to analyze the changes with regard to their implications for the TDAPA policy and propose in the next rulemaking cycle, any necessary revisions to the proposed exclusions.

We explained in the CY 2020 ESRD PPS proposed rule (84 FR 38340) that currently, 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 (83 FR 56932) for CMS to make a determination as to whether the new renal dialysis drug or biological product is eligible for the adjustment. We stated that, with regard to operationalizing the proposed exclusions, in addition to the information currently described on the CMS ESRD PPS TDAPA webpage under the Materials Required for CMS Determination Purposes, [3] we would request that the stakeholder provide the FDA NDA Type classified at FDA approval or state if the drug was approved by FDA under section 505(j) of the FD&C Act. We explained that if the FDA NDA Type assigned at FDA approval changes subsequently to the submission of the TDAPA application into CMS, we would expect that the submitter would resubmit the TDAPA request, and we would re-evaluate the submission. We noted that we plan to have quarterly meetings with FDA to discuss new renal dialysis drugs and biological products that are eligible for the TDAPA.

[3] CMS. ESRD PPS Transitional Drug Add-on Payment Adjustment. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html

We stated that, as discussed in the CY 2019 ESRD PPS final rule (83 FR 56932), once the information requested by CMS is received and reviewed, for new renal dialysis drugs and biological products eligible for the TDAPA, we will issue a change request with billing guidance that will provide notice that the product is eligible for the TDAPA as of a certain date and guidance on how to report the new drug or biological product on the ESRD claim. We noted that 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.

We also noted that for new renal dialysis drugs and biological products that are not eligible for the TDAPA, we will issue a change request that will provide notice that the drug is included in the ESRD PPS base rate, qualifies as an outlier service, and is available for use, to help ensure patients have access to the new product.

i. Proposed Exclusions from the TDAPA Eligibility

In the CY 2020 ESRD PPS proposed rule (84 FR 38341 through 38343), using the current categories in FDA/CDER MAPP 5018.2 effective November 4, 2015, we proposed to exclude Types 3, 5, 7 and 8, Type 3 in combination with Type 2 or Type 4, Type 5 in combination with Type 2, and Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8 from being eligible for the TDAPA under § 413.234(b)(1)(ii) and § 413.234(c)(1). A Type 9 NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the "parent NDA"), and the applicant does not intend to market this drug product under the Type 9 NDA after approval. We explained that we would use the NDA Classification Codes Type identified at FDA approval. If FDA changes the classification code Type after we start applying the TDAPA with respect to a particular new renal dialysis drug, we would re-evaluate TDAPA eligibility. We also proposed to exclude generic drugs from being eligible for the

TDAPA under § 413.234(b)(1)(ii) and § 413.234(c)(1).

In the following paragraphs we provide our description from the CY 2020 ESRD PPS proposed rule of each NDA Type, also referred to as NDA Classification Codes, and generic drugs that we proposed for exclusion and give our justifications for proposing that these products should not be eligible for the TDAPA for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category.

(a) Type 3 NDA – New Dosage Form

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38341), some dialysis stakeholders expressed concern that we would be paying the TDAPA for changes that did not reflect a product being significantly innovative, such as a pill size, pill scoring, oral solutions and suspensions of drugs that were previously only approved as solid oral dosage forms, time-release forms, chewable or effervescent pills, orally disintegrating granules or adsorptive changes, or routes of administration. In response to these concerns, we proposed to exclude Type 3 NDAs, which is for a new dosage form of an active ingredient that has been approved or marketed in the U.S. by the same or another applicant but has a different dosage form, as well as Type 3 in combination with Type 2 or Type 4, from being eligible for the TDAPA under § 413.234(b)(1)(ii). In addition, we proposed to exclude Type 9 NDAs, as discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), when the "parent NDA" is a Type 3 NDA.

We explained that FDA's regulation defines an active ingredient as a component of the drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (21 CFR 314.3(b), which is incorporated in FDA/CDER MAPP 5018.2).

We also explained FDA's regulation defines dosage form as the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product (21 CFR 314.3(b), which is incorporated in FDA/CDER MAPP 5018.2). This includes such factors as: (1) the physical appearance of the drug product, (2) the physical form of the drug product prior to dispensing to the patient, (3) the way the product is administered, and (4) the design features that affect the frequency of dosing.

We further stated that for Type 3 NDA drugs, the indication does not need to be the same as that of the already approved drug product. Once the new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as Type 5 NDA.

We noted that we believed that for purposes of the ESRD PPS, we do not want to incentivize the use of one dosage form of the drug over another. Even though the original product may be innovative, we would not consider making that product into a new dosage form to be innovative for purposes of the ESRD PPS. Although these drugs may provide an expansion of patient treatment options, we believed these changes are not innovative and these drugs should not be paid for using the TDAPA. We stated these drugs are still accounted for in the ESRD PPS base rate and would be eligible for an outlier payment. We noted that this type of research, development and marketing activity has been termed "product hopping" and can help manufacturers prolong revenue streams.[4] We stated that we did not believe these products should be eligible for the TDAPA because we did not want to provide perverse incentives for facilities to choose a new dosage form in order to obtain the TDAPA. In addition, we did not want to encourage the practice of companies moving drug research and development dollars

4 Reed F. Beall et al. New Drug Formulations and Their Respective Generic Entry Dates, JMCP. February, 2019, 25(2): 218-224. Available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218

from one branded drug to another, very similar drug with a longer patent life, thus increasing its market exclusivity for many years. We noted that we believed that this practice was counter to our goal of not only increasing competition among drugs in the ESRD functional categories so there are better drugs at lower cost, but also making the best use of Medicare resources and directing of those resources to payment for the utilization of high value, innovative drugs. For these reasons, we proposed to exclude Type 3 NDA drugs from being eligible for the TDAPA.

(b) Type 5 NDA – New Formulation or Other Differences

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), we proposed to exclude Type 5 NDA drugs, which can be a new formulation or new manufacturer, from being eligible for the TDAPA. In addition, we proposed to exclude Type 9 NDAs, when the "parent NDA" is a Type 5 NDA. We noted that drugs that are classified as a Type 5 NDA are sometimes referred to as reformulations or follow-on products. We explained that a Type 5 NDA is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the seven following product characteristics.

The first characteristic involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and the product is submitted as an original NDA rather than as a supplement by the applicant of the approved product.

The second characteristic is that the product is a "duplicate" of a drug product by another applicant same active ingredient, same dosage form, same or different indication, or same combination, and requires one of the following 4 items: (a) bioequivalence testing, including bioequivalence studies with clinical endpoints, but is not eligible for submission as a section 505(j) application; (b) safety or effectiveness testing because of novel inactive ingredients; (c) full safety or effectiveness testing because the product is one of the following four items: (i) is

subject to exclusivity held by another applicant; (ii) is a product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, (iii) it is a crude natural product, or, (iv) it is ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability, for example, products with different release patterns or (d) the applicant has a right of reference to the application.

The third characteristic is that the product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. We explained that this applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources. We also explained that an active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance (21 CFR 314.3(b)).

The fourth characteristic is that the product is a combination product that differs from a previous combination product by removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one of more of the active ingredients. We explained that in the case of a substitution of a noncovalent derivative of an active ingredient for one or more of the active ingredients, the NDA would be classified as a Type 2, 5 combination and we proposed to exclude it from eligibility for the TDAPA under § 413.234(b)(1)(ii).

The fifth characteristic is that the product contains a different strength of one or more active ingredients in a previously approved or marketed combination. We explained that a Type

5 NDA would generally be submitted by an applicant other than the holder of the approved application for the approved product. We also explained that a similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

The sixth characteristic is that the product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an ANDA under section 505(j) of the FD&C Act.

The seventh characteristic is that the product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, Parenteral drugs in plastic containers, and FDA/CDER MAPP 6020.2, Applications for Parenteral Products in Plastic Immediate Containers).

In the CY 2020 ESRD PPS proposed rule (84 FR 38342 through 38343) we noted that some commenters have characterized the types of drugs that are often approved in Type 5 NDAs as reformulations or line extensions. We explained that a line extension is a variation of an existing product.[5] The variation can be a new formulation (reformulation) of an existing product, or a new modification of an existing molecular entity.[6] We further explained that a line extension has been defined as a branded pharmaceutical product that: (1) includes the same active ingredient (either alone or in combination with other active ingredients) as an original product, (2) is manufactured by the same drug manufacturer that makes the original product, or

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5 V Kadiyali et al. Product line extensions and competitive market interactions: an empirical analysis. J Econometrics. 1998, 89 (1-2): 339-63.
6 S H Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, J MCP. 2005, 11(9): 746-754.

by one of its partners or subsidiaries, and (3) is launched after the original product.[7] An NME is discussed in section II.B.1.c.ii.(a) of this final rule. We noted that line extensions were few in number prior to 1984, when the Drug Price Competition and Patent Term Restoration Act was passed following public outcry over high drug prices and rising drug expenditures, and following passage of that law, line extensions became prevalent in the pharmaceutical drug industry. We also noted that we were aware that one of the acknowledged criticisms of pharmaceutical line extensions is their use as a strategy to extend the patent protections for products that have patents that are about to expire, by developing a new formulation and taking out new patents for the new formulation.[8] We stated that it has been noted that line extensions through new formulations are not being developed for significant therapeutic advantage, but rather for the company's economic advantage.[9]

We explained that we did not believe the characteristics of Type 5 NDA drugs would advance the intent of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category. We noted that we believed that while Type 5 NDA drugs may have clinical benefits to patients over previously approved products, we did not make that assessment as part of ESRD PPS payment policy. We stated that we did not believe the types of changes represented by Type 5 NDAs enhance our goal of increased competition with the overarching goal of lowering drug prices. We noted that to the contrary, it seems that a goal of line extensions can be to thwart competition. We also noted that studies indicate that there is no lowering of prices through competition from line extensions. Rather, it has been reported that

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7 A C Fowler, October 6, 2017, White Paper – Pharmaceutical Line Extensions in the United States, http://www.nber.org/aging/valmed/WhitePaper-Fowler10.2017.pdf

8 S H Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, J MCP. 2005, 11(9): 746-754.

9 R Collier Drug patents: the evergreening problem. CMAJ. 2013 Jun11; 185(9):E385-6. doi: 10.1503/cmaj.109-4466. Epub 2013 Apr 29

prices remain rigid and are not lowered. In fact, not only can product line extensions thwart competition, but they inherit the market success of the original brand, sometimes with little quality improvement over the original brand.[10] For these reasons, we explained that we did not believe providing a payment adjustment to ESRD facilities to support the uptake of a drug that is a line extension in their business model is a judicious use of Medicare resources.

We noted that a study published in February 2019, concluded that the pattern of a considerable subset of reformulations prolonged the consumption of costly brand-name products at the expense of timely market entry of low cost generics.[11] We also noted that this and other recent publications this past year have been helpful to inform policy proposals by demonstrating that reformulations frequently kept drug prices high, which does not meet our goal of increased competition assisting in the lowering of drug prices, at the expense of Medicare resources being directed to innovative drugs that advance the treatment of ESRD. Consequently, we noted that we believed it was important to propose to install guardrails to ensure that sufficient incentives exist for timely innovative drugs for the ESRD patients, that competition for lowering drug prices is not thwarted, and that perverse incentives do not exist for patients to receive a drug because it is financially rewarding, through the TDAPA, for the ESRD facilities. For these reasons, we stated that we did not believe Type 5 NDA drugs should be eligible for the TDAPA, and we proposed to exclude them in new § 413.234(e).

(c) Type 7 NDA - Previously Marketed but Without an Approved NDA

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), we proposed to exclude Type 7 NDA, which is for a drug product that contains an active moiety that has not

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10 S H Hong et al. Product Line Extensions and Pricing Strategies of Brand-Name Drugs Facing Patent Expirations, J MCP. 2005, 11(9): 746-754.

11 Reed F. Beall et al. New Drug Formulations and Their Respective Generic Entry Dates, JMCP. February, 2019, 25(2): 218-224. Available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.2.218

been previously approved in an application but has been marketed in the U.S., from being eligible for the TDAPA for renal dialysis drugs and biological products in existing functional categories. In addition, we proposed to exclude Type 9 NDAs when the "parent NDA" is a Type 7 NDA. We explained that this classification only applies to the first NDA approved for a drug product containing this (these) active moiety(ies). They include, but are not limited to the following four items: (1) The first post-1962 application for an active moiety marketed prior to 1938; (2) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation (DESI) notice (FDA's regulation at 21 CFR 310.6(b)(1) states that, "[a]n identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties"); (3) The first application for an IRS drug product first marketed after 1962; and (4) The first application for an active moiety that was first marketed without an NDA after 1962.

We stated that we did not believe the characteristics of Type 7 NDA drugs would advance the intent of the TDAPA policy because these drugs were already on the market. For example, FDA received an application for calcium gluconate, which is on the Consolidated Billing List and is already recognized as a renal dialysis service included in the ESRD PPS base rate. The NDA for calcium gluconate was classified by FDA in 2017 to be a Type 7 NDA. We stated that we believed this drug was not innovative and does not significantly advance the treatment options for ESRD. We also noted that we believed that if the Type 7 NDA drug is determined to be a renal dialysis service, it is likely it is already being used by the facility, so paying the TDAPA for it does not assist the facilities in uptake for their business model, which is one of the goals of the TDAPA. In addition, we stated that we believed paying the TDAPA for

Type 7 NDA drugs uses Medicare resources that ultimately could be used to pay for innovative drugs and services that result from research and development in areas of high value innovation. Therefore, we did not consider Type 7 NDA drugs to be eligible for the TDAPA.

(d) Type 8 NDA – Prescription to Over-the-Counter (OTC)

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38345), we proposed to exclude Type 8 NDA, which is when a prescription drug product changes to an over-the-counter (OTC) drug product, from being eligible for the TDAPA. In addition, we proposed to exclude Type 9 NDAs when the "parent NDA" is a Type 8 NDA. We explained that a Type 8 NDA is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription. We further explained that a Type 8 NDA may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

We explained that if the proposed OTC switch would apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), then FDA indicates that the application holder should submit the change as a supplement to the approved application. We noted that if the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), FDA indicates that the applicant should submit a new NDA for the OTC products, which would be classified as Type 8 NDA.

We stated that we did not believe the characteristics of Type 8 NDA drugs would advance the intent of the TDAPA policy for renal dialysis drugs and biological products in

existing functional categories because Type 8 NDAs are for drugs transitioning from prescription to OTC, and Medicare does not provide coverage of OTC drugs. We noted that we believed that although certain innovative approaches may help increase access to a broader selection of nonprescription drugs for ESRD beneficiaries, we did not consider the transition from prescription to OTC to be innovative for purposes of the TDAPA policy. We stated that we believed making the TDAPA available for Type 8 NDAs may defeat the intent of lowering overall costs for both the ESRD beneficiary and for Medicare, and was not needed by the facilities to provide additional support during an uptake period so they can be incorporated into the business model. We noted that OTC drugs have already gone through safety trials if they were previously prescription drugs and their end-point physiologic activity had been recognized and documented. Therefore, we stated that we believed the newness is a reflection of accessibility to the general public without having to obtain a prescription through a licensed practitioner. We noted that we believed these drugs, though new to the market, are not sufficiently innovative to qualify for TDAPA eligibility.

(e) Generic Drugs

We proposed to exclude drugs approved by FDA under section 505(j) of the FD&C Act, which are generic drugs, from being eligible for the TDAPA. As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38337 through 38339), an ANDA is an application submitted by drug manufacturers and approved by FDA under section 505(j) of the FD&C Act for a duplicate of a previously approved drug product.

We explained that an ANDA generally must contain information to show that the proposed generic product: (1) is the same as the reference listed drug (RLD) with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, and

labeling (with certain permissible differences) and (2) is bioequivalent to the RLD. See section 505(j)(2)(A) of the FD&C Act. In general, an ANDA would not be appropriate if clinical investigations are necessary to establish the safety and effectiveness of the proposed product. A drug product approved in an ANDA is presumed to be therapeutically equivalent to its RLD. A drug product that is therapeutically equivalent to an RLD can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling.

We noted that, in the CY 2019 ESRD PPS final rule (83 FR 56931), we included generic drugs in the definition of a new renal dialysis drug or biological product eligible for the TDAPA because we believed this would foster both a competitive marketplace and innovation of drugs within functional categories, mitigate high launch prices, and provide a financial boost to support utilization. We explained that during the CY 2019 ESRD PPS rulemaking, we were aware of the pricing strategies being used by certain pharmaceutical companies to block the entry of generic drugs into the market in order to keep drug prices high. Though generic drugs are not considered innovative products, our primary intent in making generic drugs eligible for the TDAPA was to increase competition so that drug prices would be lower for the beneficiary. We then noted that we have since learned that bringing more generic drugs to market, though a significant component in lowering drug prices, is not in and of itself the solution.

We discussed a June 2018 report that examined increased generic drug competition as the primary impetus to curtail skyrocketing drug prices, and found that though it is helpful, there is a ceiling on its impact. It found that generic competition would not affect 46 percent of the estimated sales revenue of the top 100 drugs through 2023.[12]

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12 B Isgur et al., Health Research Institute, The FDA is approving more generic drugs than ever before. Faster than

We also discussed a June 2018 article, which noted that competition has a limited impact on American health care, particularly when it comes to expensive interventions like prescription drugs. The article noted that when an expensive drug's competition within the same family of drugs came on the market the prices did not go down. Rather, the prices increased approximately 675 percent. Each new entrant cost more than its predecessors, and their makers then increased their prices to match the newcomer's. The article stated that when the first generic finally entered the market, its list price was only slightly less at 539 percent above the original entrant. It stated that economists call this "sticky pricing" and the article noted that this is common in pharmaceuticals, and has raised the prices in the U.S. of drugs for serious conditions even when there are multiple competing drugs. Compounding this problem, the article stated that companies have decided it is not in their interest to compete.[13]

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38344) that for purposes of the ESRD PPS, we believed that we need to strike a balance between enhancing significant renal dialysis drug innovation and encouraging competition through support of innovative drugs that would become optimal choices for ESRD patients and advance their care through improved treatment choices. We noted that we believed that our goal in supporting competition among drugs in the ESRD PPS functional categories was to ultimately affect the launch price of new drugs. We stated that we questioned whether including all new renal dialysis drugs and biological products as eligible for the TDAPA would help us meet that goal. We expressed that reining in launch prices by placing guardrails on line extensions, reformulations and "sticky pricing" while staying mindful of the Medicare trust fund would better enable us to achieve our

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ever before. Is it enough to lower drug costs? June 2018. Available at: https://www.pwc.com/us/en/health-industries/health-research-institute/pdf/pwc-health-research-institute-generic-drug-pricing-june-2018.pdf.

13 E Rosenthal, New York Times, Why Competition Won't Bring Down Drug Prices. June 21, 2018. Available at: https://www.nytimes.com/2018/06/21/opinion/competition-drug-prices.html

goals for the TDAPA policy.

Therefore, we proposed to revise the drug designation process regulation at § 413.234 by revising paragraph (b)(1)(ii) and adding paragraph (e), effective January 1, 2020, to specify that a new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the TDAPA if it is a generic drug or if the NDA for the drug is classified by FDA as a certain Type—specifically, if the drug is approved under section 505(j) of the FD&C Act or the NDA for the drug is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 4, or Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8.

We solicited comments as to whether any NDA Types that would remain eligible for the TDAPA under our proposal should be excluded, and whether any NDA Types that we proposed to exclude should be included, for example, within the NDA Type 3 (new dosage form) the inclusion of IV to oral route of administration.

ii. Examples of New Renal Dialysis Drugs and Biological Products that Would Remain Eligible for the TDAPA

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38344) that under our proposal, any new renal dialysis drug or biological product that we did not propose for exclusion, would continue to be eligible for the TDAPA. In the CY 2020 ESRD PPS proposed rule (84 FR 38344 through 38346), we provided some examples of the types of renal dialysis drugs and biological products that we believed would continue to be eligible for the TDAPA under our proposal, using the descriptions in the NDA Classification Codes referenced in the CY 2020 ESRD PPS proposed rule (84 FR 38339 through 38341). We noted that under our proposal, BLAs approved by FDA under section 351 of the PHS Act, which include biological products

and biological products that are biosimilar to, or interchangeable with, a reference biological product, also would continue to be eligible for the TDAPA.

(a) Type 1 NDA – New Molecular Entity

In the CY 2020 ESRD PPS proposed rule (84 FR 38344), we explained that a Type 1 NDA refers to drugs containing an NME. We further explained that an NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505(b) of the FD&C Act or has been previously marketed as a drug in the U.S.

We stated that we believed the new renal dialysis drugs that are classified by FDA as a Type 1 NDA should continue to be eligible for the TDAPA because they generally fall within the 505(b)(1) pathway typically used for novel drugs, meaning they have not been previously studied or approved, and their development requires the sponsor to conduct all studies needed to demonstrate the safety and efficacy of the drug. We noted that unlike the drugs proposed to be excluded from the TDAPA as described above, these drugs are generally not line extensions of previously existing drugs. We stated that we believed there will be expenses with uptake by ESRD facilities of Type 1 NDA drugs, and one of the goals of the TDAPA is to provide additional support to ESRD facilities during the uptake period for these innovative drugs and help incorporate them into their business model.

(b) Type 2 NDA – New Active Ingredient

In the CY 2020 ESRD PPS proposed rule (84 FR 38344 through 38345), we explained that a Type 2 NDA is for a drug product that contains a new active ingredient, but not an NME. We further explained that a new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or

noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. Furthermore, if the active ingredient is a single enantiomer and a racemic mixture (the name for a 50:50 mixture of 2 enantiomers) containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a Type 2 NDA. Enantiomers are chiral molecules that are non-superimposable, mirror images of one another.

We stated that we believed the new renal dialysis drugs classified by FDA as Type 2 NDAs should be eligible for the TDAPA because, in part, it covers a single enantiomer active ingredient for which a racemic mixture containing that enantiomer has been approved by FDA. We noted that single enantiomer drugs can lead to fewer drug interactions in the ESRD population, which already has a significant medication burden.[14] We stated that we believed these drugs are innovative and it is important to support their development because of their lower development cost burden, coupled with enhancement of patient choice, which supports not only innovation, but the ability of the product to successfully launch and compete. We noted that we believed having the Type 2 NDA drugs be eligible for the TDAPA would support our goal of providing support to the ESRD facilities for 2 years while the drug is being incorporated into their business model.

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14 A Calcaterra and I D'Acquarica, J Pharmaceutical and Biomedical Analysis, "The market of chiral drugs: Chiral switches versus de novo enantiomerically pure compounds," 147(2018). Pages 323-340. Available at: https://www.sciencedirect.com/science/article/pii/S0731708517314838?via%3Dihub.

(c) Type 4 NDA – New Combination

In the CY 2020 ESRD PPS proposed rule (84 FR 38345), we explained that a Type 4 NDA is a new drug-drug combination of two or more active ingredients. We further explained that an application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient.

We proposed that new renal dialysis drugs that are classified as a Type 4 NDA should continue to be eligible for the TDAPA if at least one of the components is a Type 1 NDA (NME) or a Type 2 NDA (new active ingredient), both of which merit the TDAPA as previously discussed. We stated that we believed that an added advantage is that while introducing an innovative product, which is not the case for Type 3 NDA drugs, it reduces the pill burden to a patient population challenged with multiple medications and a complex drug regimen. We noted that medication adherence is thought to be around 50 percent in the dialysis population and reducing this burden can improve adherence and should lead to improvement in treatment outcomes.[15]

We noted that we believed the advantages of Type 1 NDA and Type 2 NDA drugs, coupled with the possibility of improved adherence, merits eligibility for the TDAPA in that it encourages both innovators to develop competitive drugs at lower prices for this NDA Type, and ESRD facilities to use the products with the boost that the TDAPA will provide in facilitating uptake of these new products.

(d) Type 9 NDA - New Indication or Claim, Drug not to be Marketed under Type 9 NDA After Approval

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15 K Parker et al., Medication Burden in CKD-5D: Impact of dialysis modality and setting, Clin Kidney J. 2014, 7: 557-561. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389130/pdf/sfu091.pdf

In the CY 2020 ESRD PPS proposed rule (84 FR 38345), we explained that a Type 9 NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the "parent NDA"), and the applicant does not intend to market this drug product under the Type 9 NDA after approval. We explained that a Type 9 NDA is generally submitted as a separate NDA so as to be in compliance with the guidance for industry on Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.[16] When the Type 9 NDA is submitted, it is given the same NDA Type as the pending NDA. When one application is approved, the other application will be reclassified as a Type 9 NDA regardless of whether it was the first or second NDA actually submitted. After the approval of a Type 9 NDA, FDA will "administratively close" the Type 9 NDA and thereafter only accept submissions to the "parent" NDA.

We stated that we believed that since Type 9 NDA is a new clinical indication, this suggests that a drug manufacturer is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs, and we consider this to be sufficiently innovative to warrant TDAPA eligibility.

We noted that we believed renal dialysis drugs that are classified as NDA Types 1, 2, and 4 are all innovative and therefore we proposed that these drugs should continue be eligible for the TDAPA. We stated that when the "parent NDA" is Type 1, 2, or 4, Type 9 NDA would be a new indication of those innovative drugs. Therefore we expressed that the Type 9 NDA, when the "parent" is Type 1, 2, or 4, is just as innovative as Type 1, 2, or 4 and therefore should also be eligible for the TDAPA. We noted that we believed applying the TDAPA with respect to

16 FDA. Guidance for Industry. Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

Type 9 NDA new renal dialysis drugs would assist ESRD facilities in adopting these drugs into their treatment protocols for patients, when these drugs are warranted for use in that subset of patients.

(e) Type 10 NDA - New Indication or Claim, Drug to be Marketed under Type 10 NDA After Approval

In the CY 2020 ESRD PPS proposed rule (84 FR 38345), we explained that a Type 10 NDA is for a drug product that is a duplicate of a drug product that is the subject of either a pending or approved NDA, and the applicant intends to market the drug product under this separate Type 10 NDA after approval. We further explained that a Type 10 NDA is typically for a drug product that has a new indication or claim, and it may have labeling and/or a proprietary name that is distinct from that of the original NDA. When the Type 10 NDA is submitted, it would be given the same NDA Type as the original NDA unless that NDA is already approved. When one application is approved, the other would be reclassified as Type 10 NDA regardless of whether it was the first or second NDA actually submitted.

We stated that we believed renal dialysis drugs with the Type 10 NDAs are sufficiently innovative and should be eligible for the TDAPA because a new indication for a previously submitted drug that is applicable to renal dialysis advances the field and suggests the drug manufacturer is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs. We noted that we believed this could provide savings in terms of time-to-market and research and development, which could be reflected in the launch price of the drug. We further stated that we believed applying the TDAPA with respect to Type 10 NDA new renal dialysis drugs will assist ESRD facilities in adopting these drugs into their treatment protocols for patients when these drugs are warranted for use in that

subset of patients.

(f) FDA Approvals of BLAs submitted under section 351 of the PHS Act

In the CY 2020 ESRD PPS proposed rule (84 FR 38346), we stated that under our proposal, products that are licensed under section 351 of the PHS Act, which occurs for biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, would continue to be eligible for the TDAPA.

We explained that a BLA submitted under section 351(a) of the PHS Act is a "stand-alone BLA" that contains all information and data necessary to demonstrate that (among other things) the proposed biological product is safe, pure, and potent.

We explained that an application for licensure of a proposed biosimilar biological product submitted in a BLA under section 351(k) of the PHS Act must contain information demonstrating that the biological product is biosimilar to a reference product. 'Biosimilar' means "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" (see section 351(i)(2) of the PHS Act).

We explained that an application for licensure of a proposed interchangeable product submitted in a BLA under section 351(k) of the PHS Act must meet the standards for "interchangeability." To meet the standards for "interchangeability," an applicant must provide sufficient information to demonstrate biosimilarity, and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological

product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act). Interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider (see section 351(i)(3) of the PHS Act). Further information regarding biosimilar biological products is available on the FDA website.[17]

We stated that CMS continues to support the development and the utilization of these products that contain innovative technology for the treatment of ESRD. We explained that the process for licensure of biosimilar biological products is a different pathway than that for generic drugs and has different requirements. We noted that we believed that a categorical exclusion from TDAPA eligibility for all biological products that are biosimilar to or interchangeable with a reference biological product, would disadvantage this sector of biological products in a space where we are trying to support technological innovation. While the products themselves are highly similar to the reference biological product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biosimilar biological product and the biological reference product in terms of the safety, purity, and potency of the product, CMS believes the technology used to develop the products is sufficiently new and innovative to warrant TDAPA payment at this time.

However, we noted that unlike NDAs submitted pursuant to sections 505(b)(1) or 505(b)(2) of the FD&C Act, we did not have a categorical system to use as a proxy for assistance in determining which types of applications would meet the intent of the TDAPA policy. Therefore, we proposed to continue to allow all biological products that are biosimilar to or interchangeable with a reference biological product to remain eligible for the TDAPA instead of

[17] https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

proposing to exclude all of them.

In the CY 2020 ESRD PPS proposed rule (84 FR 38346), we noted that we were aware that there are similar concerns about providing the TDAPA for these products that there are with generic drugs. Specifically, we explained that according to a recent report, increased drug class competition for biosimilar biological products has not translated into pricing reductions, and there was a market failure contributing to the rising costs of prescription drugs. The researchers noted that the increases were borne solely by Medicare. [18] We stated that we would continue to monitor future costs of biosimilar biological products as they pertain to renal dialysis, the TDAPA, and the ESRD PPS.

With regard to new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, we stated that we believed continuing to include these drugs and biological products as eligible for the TDAPA focuses payment to those products that are innovative in a way that meets the intent of the adjustment. That is, our intention is to support innovation by helping ESRD facilities make appropriate changes in their businesses to adopt such products, provide additional payment for such associated costs, incorporate these drugs and biological products into their beneficiaries' care plans and potentially promote competition among drugs and biological products within the ESRD PPS functional categories. We stated that we planned to continue to monitor the use of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category and will carefully evaluate the products that qualify for the payment adjustment. We noted that for new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional

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18 A San-Juan-Rodriguez et al. "Assessment of Price Changes of Existing Tumor Necrosis Factor Inhibitors After the Market Entry of Competitors." JAMA Intern Med 2019. Feb18 https:jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724390.

category, the purpose of the TDAPA continues to be a pathway toward a potential base rate modification.

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38344), that compared to the TDAPA policy finalized in the CY 2019 ESRD PPS final rule, we believed that these proposed revisions would reduce CY 2020 Medicare expenditures for new renal dialysis drugs and biological products, which would also have a better downstream impact for beneficiary co-insurance. Specifically, we noted that under the expanded policy finalized in the CY 2019 ESRD PPS final rule (83 FR 56932), effective January 1, 2020, the TDAPA would apply for all new renal dialysis drugs and biological products. We stated that we believed that since our proposed policy would carve out certain drug types from being eligible for the TDAPA and would be more limited than the expansive policy finalized in the CY 2019 ESRD PPS final rule for CY 2020, there would be lower Medicare expenditures in CY 2020. Further, the downstream effect of lower Medicare expenditures is lower co-insurance for beneficiaries.

We stated that based on our past experience and our expectation of detailed analysis of future drug product utilization, pricing and payment, we anticipated proposing further refinements to the TDAPA policy through notice and comment rulemaking in the future.

Commenters generally supported our proposal to refine the TDAPA eligibility criteria to target more innovative drugs and biological products. However, they had specific suggestions regarding changes to the proposal. For example, commenters provided suggestions for renal dialysis drugs and biological products that should be excluded (biosimilar biological products), included (first ESRD new indication), and other eligibility criteria (SCI).

The comments and our responses to the comments on our proposal to rely on, as a proxy, the NDA Classification Codes, as well as the proposal for updating the TDAPA exclusions when

FDA makes changes to the NDA Classification Codes, are set forth below.

Comment: MedPAC commended CMS for reconsidering the TDAPA eligibility criteria and proposing a standard that is stricter than the one the agency adopted in the CY 2019 ESRD PPS rulemaking. Several commenters supported the use of the TDAPA for encouraging the adoption of new and innovative renal dialysis products by ESRD facilities, and encouraged us to finalize the proposal to exclude drugs for which the NDA Types are for products that are not truly innovative. They recommended that CMS describe when a drug or biological product is considered to be truly innovative. If a product qualifies, it should receive the TDAPA. One drug manufacturer specifically supported CMS's proposal to use NDA Classification Codes to establish TDAPA eligibility, and to maintain eligibility for drugs approved through NDA Types 1, 2, 4, 9, and 10. One national dialysis association noted that the NDA Classification Codes seem to be reasonable proxies for exclusion of products from TDAPA that are technically "new" but not necessarily truly innovative. Commenters who supported the use of the NDA Classification Codes recognized that the codes could change and understood we would consider potential revisions to the regulatory language in that case.

However, one drug manufacturer noted that the NDA Classification Codes are contained in an FDA MAPP that is not subject to public notice, input, or comment, and that can be changed at any time by FDA without providing notice to or seeking input from stakeholders or from CMS. The manufacturer noted that the NDA Classification Codes are not codified in any statutory or regulatory provision and were created solely for FDA's administrative purposes, without any relevance to assessments of innovativeness or therapeutic value.

A drug manufacturer did not support CMS' proposal to exclude certain NDA Types from TDAPA eligibility. The company stated the FDA's NDA Classification Codes are a blunt

instrument and an inadequate standard on which to judge innovativeness. In addition, the company stated that the proposal pegs the use of NDA Classification Codes to the version dated November 4, 2015 and makes no provision for an updated future version of such codes.

Response: We appreciate the supportive comments regarding our TDAPA proposal and specifically our proposed reliance on the FDA NDA Classification Codes as a proxy. We also appreciate the supportive comments about our proposal to analyze any changes that FDA makes to the NDA Classification Codes when they are publicly available and propose in the next ESRD PPS rulemaking cycle any necessary revisions to the TDAPA exclusions.

Regarding the comments that FDA created the NDA Classification Codes for administrative purposes and they should not be used to assess innovativeness or therapeutic value, and the comment requesting that we describe when a drug or biological product is considered to be truly innovative, we believe FDA's NDA Classification Codes provide an objective basis that we can use to distinguish innovative from noninnovative renal dialysis drugs and biological products. That is, using the NDA Classification Codes will help us in our effort to support innovation by directing Medicare resources to innovative renal dialysis drugs and biological products, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost.

We acknowledge that the NDA Classification Codes are not subject to public notice, input, or comment, and can be changed at any time by FDA without providing notice to or seeking input from stakeholders or from CMS. As discussed in section II.B.1.b of the CY 2020 ESRD PPS proposed rule, the Classification Codes assigned to an NDA generally describe FDA's classification of the relationship of the drug to drugs already marketed or approved in the

U.S. As we discussed in the CY 2020 ESRD PPS proposed rule, if FDA makes changes to the NDA Classification Codes in FDA/CDER MAPP 5018.2, we would assess FDA changes at the time they are publicly available and we would analyze those changes with regard to their implications for the TDAPA policy under the ESRD PPS. We would plan to propose any necessary language revisions to the exclusions set forth in proposed § 413.234(e) in the next rulemaking cycle.

Comment: Many commenters appreciated CMS addressing the concerns raised by stakeholders regarding the all-inclusive approach to TDAPA eligibility finalized in the CY 2019 ESRD PPS final rule. They stated we should finalize the use of the FDA NDA Classification Codes as proposed, with one modification. Specifically, if a product falls into an excluded NDA Type, but obtains FDA approval for its first ESRD new indication, regardless of its NDA designation, that product should be eligible for TDAPA. These commenters stated that without such modification, using the NDA Classification Codes has the significant potential to exclude from TDAPA eligibility truly new and innovative drugs for ESRD patients.

Some commenters noted that CMS recognizes in its discussion of the Type 10 NDA that a new ESRD indication for a previously approved non-ESRD drug advances the field and presents a new approach to provide care for ESRD patients. The commenters stated that not all products for which a manufacturer obtains a new ESRD indication will be approved through a Type 10 NDA. For example, a product originally approved for a non-ESRD indication through an excluded NDA Type, may have a first ESRD new indication added through an NDA supplement to that NDA, thus resulting in the new ESRD product being excluded from TDAPA eligibility. The commenters asserted that the innovation and investment by this manufacturer to obtain the first ESRD new indication is no less than that of the manufacturer who submits a Type

10 NDA for a new indication, but CMS's proposed criteria would exclude such a drug from TDAPA eligibility. The commenters stated that, by definition, a first ESRD new indication denotes that the product has not been approved for this population previously and is consistent with CMS's intent to limit the TDAPA to truly innovative products.

An ESRD facility and a national dialysis association expressed concerns regarding CMS's proposal to exclude FDA NDA Type 5 and Type 7 from TDAPA eligibility. Regarding Type 5, they believe that new drug formulations may offer specific benefits to patients. For example, they stated that if phosphate binders currently marketed in tablet form were to become available in a topical form, it might offer benefits like decreased satiety and decreased pill burden, which could lead to improved compliance with the medications and increased protein intake, which has been associated with better outcomes for patients with ESRD treated by maintenance dialysis. Regarding Type 7, commenters agreed with CMS that if a drug is being used by an ESRD facility, there is no need for additional payment in the form of TDAPA. However, they believe there should be a requirement to verify that use before CMS concludes that the drug is not eligible.

A few commenters noted that the proposed exclusions would remove from TDAPA eligibility important therapeutic advances that may happen to be new formulations, new indications, and new dosage forms, which can make it easier for the patient to adhere to prescribed therapy and offer significant value in increased quality of life. Commenters noted that the proposal would exclude, for example, a drug that receives a new ESRD indication or is a reformulation that results in a patient needing only one, rather than several doses a day, requiring the patient to be awoken multiple times during the night. They stated that to exclude such new drugs and biological products from TDAPA eligibility could erect barriers to patient use and

chill new research into the entire category of ESRD medicine, and would be a great disservice to patients, providers, and the Medicare program, as it would inhibit the ability of physicians and ESRD facilities to incorporate these innovative new therapies into the care of and treatment protocols for their patients with ESRD. In contrast, one non-profit provider association expressed support for CMS's proposal to exclude line extensions from TDAPA eligibility.

One drug manufacturer stated the proposed approach imposes a framework that would categorically exclude many types of innovative new drugs from TDAPA eligibility. For example, the manufacturer stated that a new drug potentially may be assigned a Type 3 or Type 5 NDA by FDA, even if FDA reviews and approves the product under an original NDA through the 505(b)(1) pathway, and even if the drug reflects innovative characteristics and facilitates important benefits, such as improving patient outcomes through safety or efficacy advantages, reducing harmful complications, or providing patients (including specific subpopulations of patients) with new treatment options and/or new access options. The drug manufacturer stated that our proposed approach would impair providers' ability to evaluate and incorporate these important types of innovative new medicines into their practice, and would have detrimental access implications for patients. As such, it would undermine the goals that CMS seeks to achieve through TDAPA with respect to facilitating innovation, competition, and the ability of ESRD facilities to test and accommodate new therapies in their care plans. The drug manufacturer strongly encouraged CMS to modify the proposed criteria to allow for TDAPA eligibility for Type 3 and Type 5 NDAs, noting that new dosage forms and new formulations (among other differences), particularly for IV and injectable products, reflect significant innovation and lead to new access options and treatment flexibility for patients.

One drug manufacturer urged CMS to adopt the modification that a Type 5 drug should

be eligible for TDAPA if it contains a previously approved active moiety and obtains approval for an ESRD-related indication for which the active moiety was not previously approved. The drug manufacturer asserted that, to achieve a new indication, a manufacturer will be required to invest the same resources and perform the same research and development, whether the new indication is approved through a Type 10 NDA or a different pathway, such as a supplement to the original NDA.

The commenter noted that there are a myriad of considerations that go into any particular drug's FDA approval pathway. Because the reasoning to include "Type 5" for a new indication is similar to that for including Type 10 NDA, the commenter strongly urged CMS to also include Type 5 new indication. The commenter stated that providing TDAPA eligibility when a drug containing a previously approved active moiety is approved for an ESRD indication for which such active moiety was not previously approved—regardless of NDA type—would also encourage manufacturers to pursue development strategies that capitalize on the benefits of expanding uses for current treatments into new indications in the ESRD space. The drug manufacturer urged CMS to recognize that a previously approved drug product that later becomes approved for an ESRD indication should be eligible for TDAPA.

Response: We thank commenters for the helpful comments and suggestions. With regard to the suggestions that we allow new renal dialysis drugs and biological products that have a new indication for "ESRD" or "ESRD-related" conditions to be eligible for the TDAPA, we understand this to mean that the drug was not previously indicated for a condition or conditions associated with ESRD, but after clinical trials, the drug has been proven to be safe and efficacious for the treatment or management of a condition or conditions associated with ESRD, and the drug falls within an ESRD PPS functional category.

At this time, we do not believe that making a first ESRD new indication for a Type 5 NDA drug eligible for the TDAPA is consistent with CMS's intent to limit the TDAPA to truly innovative products. We believe that while Type 5 NDA drugs may have clinical benefits to patients over previously approved products, we did not make that assessment as part of ESRD PPS payment policy because these are drugs that are currently on the market but may have been reformulated or may be line-extensions. We do not believe that the characteristics of Type 5 NDA drugs would advance the intent of the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category. As we stated in section II.B.1.c.i.(b) of the CY 2020 ESRD PPS proposed rule (84 FR 38342), we do not believe that the types of changes represented by Type 5 NDAs enhance our goal of increased competition with the overarching goal of lowering drug prices. To the contrary, it seems that a goal of line extensions can be to thwart competition. Studies indicate that there is no lowering of prices through competition from line extensions. Rather, it has been reported that prices remain rigid and are not lowered. In fact, not only can product line extensions thwart competition, but they inherit the market success of the original brand, sometimes with little quality improvement over the original brand. We believe making Type 5 NDA drugs eligible for the TDAPA, even for the first ESRD new indication, may cause more attention to be diverted to the less costly duplication of drugs that are already available rather than those that may be more expensive to develop and bring to market. In addition, this could cause an influx of non-innovative drugs to the dialysis space, potentially crowding out innovative drugs. For these reasons, we continue to believe that providing the TDAPA to ESRD facilities to support the uptake of a drug reflected in an ESRD PPS functional category that may be a line extension or reformulation in their business model is not a judicious use of Medicare resources.

In response to the commenter suggesting that Type 5 NDA drug products are the same as Type 10 NDA drug products, we believe that they are distinct in that Type 5 NDAs are reformulations or line extensions that are not truly innovative and Type 10 NDA drug products are not. As we discussed in the CY 2020 ESRD PPS proposed rule in section II.B.1.c.ii.(e) (84 FR 38345), we believed that Type 10 NDA drug products are sufficiently innovative because a new indication for a previously submitted drug that is applicable to renal dialysis advances the field and suggests the drug manufacturer is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs. We noted that we believed this could provide savings in terms of time-to-market and research and development, which could be reflected in the launch price of the drug. We further stated that we believed applying the TDAPA with respect to Type 10 NDA new renal dialysis drugs will assist ESRD facilities in adopting these drugs into their treatment protocols for patients when these drugs are warranted for use in that subset of patients.

In addition, as we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38340), we believe FDA's NDA Classification Codes provide an objective basis that we can use to distinguish innovative from noninnovative renal dialysis service drugs. We believe that distinguishing drugs in this categorical manner helps us in our effort to support innovation by directing Medicare resources to renal dialysis drugs and biological products that are not reformulations or new dosage forms, while simultaneously balancing our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost. We also believe that including some characteristics of an NDA Type without including others undermines the objective basis of the use of this system as a proxy to determine if a new renal dialysis drug or biological product is

innovative for the purposes of the TDAPA.

The NDA Classification Code Type 7 is a drug that has been previously marketed but without an approved NDA. With regard to the suggestion that we verify ESRD facility use of a Type 7 drug before deciding that the drug is ineligible for the TDAPA, we do not believe the characteristics of Type 7 would advance the intent of the TDAPA policy because these drugs are already on the market and may already be in use in the ESRD facilities. Thus, providing the TDAPA for Type 7 NDA drugs would not assist the facilities in their uptake for their business model.

With regard to the comment about a drug currently marketed in tablet form that becomes available in a topical form, we believe the commenter is actually referring to Type 3 NDA, which is an NDA Classification Code that we are excluding from the TDAPA. Regarding the comments about excluding line extensions such as new formulations (Type 5) and new dosage forms (Type 3), we do not believe these drugs are sufficiently innovative to warrant TDAPA eligibility and we do not want to provide perverse incentives for ESRD facilities to choose a new dosage form in order to obtain the TDAPA. Although these drugs may provide an expansion of patient treatment options, we continue to believe that these changes are not innovative and should not be eligible for the TDAPA for new renal dialysis drugs and biological products in existing functional categories.

Regarding the comments about erecting barriers to patient use, chilling new research into ESRD medicine, and inhibiting the ability of physicians and ESRD facilities to incorporate these innovative new therapies into treatment protocols for their ESRD patients, we note that beneficiaries have access to all FDA-approved drugs and biological products for renal dialysis services, regardless of whether the ESRD facility receives TDAPA or not. The TDAPA

eligibility does not prevent patient access to any renal dialysis services. ESRD patients currently have, and will continue to have access to all FDA-approved renal dialysis drugs and biological products. Our policy would not prevent a physician from determining that the new Type 3 drug facilitates additional benefits. Such benefits could include improving patient outcomes through safety or efficacy advantages, reducing harmful complications, or providing patients with new treatment options over and above what is currently available. Then, the physician could include the drug in a patient's plan of care for the ESRD facility to furnish to that patient. We note that because Type 3 drugs would not eligible for the TDAPA, there would be no additional co-insurance for the beneficiary. We continue to believe that the TDAPA for renal dialysis drugs and biological products that fall within an ESRD PPS functional category should be applied only to truly innovative drugs and biological products. We thank and agree with the non-profit provider association that expressed support for our proposal to exclude line extensions from TDAPA eligibility.

After careful consideration of the comments, we are finalizing our proposal to exclude certain NDA types from TDAPA eligibility. That is, we are finalizing to exclude Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8.

Comment: A physician association expressed support for the proposal to revise the TDAPA eligibility criteria but stated it is critical for CMS to support and specifically focus on innovations that also pertain to the pediatric space. The association noted that new products and therapies that come to market are not always tested in the pediatric population, and policies must be put in place to change this moving forward. The association emphasized that children and adolescents are not simply "little adults." Rather, they have a unique physiology characterized

by maturing organ function, body metabolism, and body distribution characteristics distinct from what adults manifest. Due to these differences, the association noted, the safety and efficacy data developed for adults and only studied in adults may not be appropriate for pediatric patients. The association recognized that the small number of pediatric patients complicates conducting safety, efficacy, or interventional trials in children, but noted this data is crucial to allow children to also benefit from innovation.

Response: We thank the physician association for its support for the refinement of TDAPA eligibility and for its comments regarding the pediatric dialysis population. We recognize that the pediatric dialysis population has unique needs and that those needs must be closely examined. Our data analysis contractor will be holding a Technical Expert Panel meeting in December 2019 and intends to facilitate discussions on the topic of pediatric dialysis.

Comment: Some commenters strongly encouraged CMS and FDA to work together to: (i) provide greater transparency into the NDA Type decision; and (ii) develop a process for manufacturer involvement in that decision. A commenter also suggested that a formal process be adopted to request and appeal NDA Type classification decisions.

Response: We have been conferring with FDA regarding new and innovative renal dialysis products, and intend continue to work with FDA in the future to discuss NDA Types as they pertain to new renal dialysis drugs and biological products. It is our understanding that FDA will meet with drug manufacturers for discussions regarding the NDA Types that may be considered for their applications.

Comment: MedPAC, a professional association and 2 pharmaceutical companies commented that they disagreed with and did not support the proposal to use the NDA Classification Codes to determine TDAPA eligibility for new renal dialysis drugs, arguing that

this is not an appropriate or well-suited proxy for determining TDAPA eligibility. They stated that they did not support CMS's proposed approach to judge the innovativeness of drugs. MedPAC commented that an SCI standard would be the best way to ensure taxpayer and beneficiary dollars are spent to improve patient care or outcomes. MedPAC noted that using a clinical improvement standard for the TDAPA policy would be consistent with: (1) Medicare's payment for certain new technologies under the outpatient PPS (OPPS) and inpatient PPS (IPPS); and (2) CMS's proposal to apply the IPPS SCI standard (specified in § 412.87(b)(1)) to the add-on payment for new ESRD equipment and supplies.

MedPAC asserted that to protect the well-being of beneficiaries and ensure good value for the Medicare program and taxpayers, Medicare should not pay more for drug or biological products that have not yet been proven to provide better outcomes for beneficiaries. Therefore, MedPAC noted, a new drug or biological product should not qualify for the TDAPA if there is no evidence that it is an improvement relative to existing care. Similarly, a large dialysis organization (LDO) requested a patient-centered approach to TDAPA eligibility with clear evidence of an improvement in one or more patient-centered outcomes. The LDO suggested that CMS could structure a TDAPA clinical improvement standard similar to the standard that the agency uses to pay for new technologies under the IPPS (specified in § 412.87(b)(1)).

MedPAC stated that CMS's approach relies on FDA approval pathways using a standard that is less stringent than a clinical improvement standard for all drugs and biological products that fit into an ESRD functional category, and should not be used, because on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries. The Commission also asserted that the Medicare program, not FDA, should adjudicate spending determinations based on the specific needs of the Medicare

population. MedPAC stated that the evaluation of the evidence of whether a new drug or biological product improves Medicare beneficiaries' outcomes should rest with CMS. One non-profit provider association and an LDO suggested the proposed policy could go further by also addressing whether new drugs for renal care represent an SCI, and that the proposed policy stands in contrast to the more robust policy that CMS proposed for new equipment and supplies based on the Medicare IPPS new technology add-on payment. These commenters stated that while it is expected that some drugs with a new molecular entity or new active ingredient will represent an SCI, not all will. They urged CMS to also consider whether a new drug or biological product addresses the needs of a patient population unresponsive to, or ineligible for, currently available treatments, or significantly improves clinical outcomes for a patient population compared to currently available treatments. They maintained that CMS' TDAPA policy should spur innovation by targeting products that do more than offer minor, if any, clinical improvement. For example, a drug that significantly improves compliance because it is not accompanied by complications such as gastrointestinal effects, which can deter patient compliance, might warrant eligibility for TDAPA and higher payment. The commenters suggested that CMS should consider refining TDAPA eligibility based on its own assessment of a product's clinical significance, similar to its proposed approach for the TPNIES.

One drug manufacturer commented that relying on NDA Classification Codes for TDAPA eligibility would significantly discourage investment in the ESRD space. The manufacturer argued that the proposed changes would create a rigid and narrow set of criteria for TDAPA eligibility that would significantly limit the chances for new products to qualify for the opportunity to be evaluated and incorporated into ESRD care plans. The manufacturer expressed concern that innovators will be discouraged from investing time and resources in ESRD research,

development, and innovation, because product uptake potential will be uncertain and unlikely. That, in turn, would also result in reduced competition, to the further detriment of ESRD stakeholders and the Medicare program, according to the commenter.

Response: We appreciate the thoughtful and insightful comments from MedPAC and other commenters. With regard to MedPAC not supporting our proposed approach to judge the innovativeness of drugs, and noting that an SCI standard is the best way to ensure taxpayer and beneficiary dollars are spent to improve patient care or outcomes, we respectfully disagree.

We believe that using the NDA Classification Codes will help us to objectively distinguish drugs that would assist our efforts to support innovation by directing Medicare resources to those new renal dialysis drugs and biological products. We also believe that our proposed approach would promote our goal to foster competition within the ESRD PPS functional categories by supporting products that advance the treatment for ESRD beneficiaries at a lower cost. Additionally, our proposed approach would promote our goal of providing a transition period for the unique circumstances experienced by ESRD facilities and to allow uptake of the new product. That is, our intention is to support innovation by helping ESRD facilities make appropriate changes in their businesses to adopt such products, provide additional payment for such associated costs, incorporate these drugs and biological products into their beneficiaries' care plans and potentially promote competition among drugs and biological products within the ESRD PPS functional categories. We proposed to narrow the types of new renal dialysis drugs and biological products within the ESRD PPS functional groups that are eligible for TDAPA, effective January 1, 2020. To do so, we proposed to extend TDAPA eligibility to those renal dialysis products that are new and innovative, not just new, based on the FDA's NDA Classification Code used for investigational product review. As detailed in the CY

2020 ESRD PPS proposed rule, we believe that the NDA classifications that we are excluding, which includes Type 3 (new dosage forms) are not innovative.

With regard to having an SCI standard, as we discuss in section II.B.1.c of this final rule, we continue to believe that unlike many Medicare beneficiaries, the Medicare ESRD beneficiary is significantly complex, with each patient having a unique and challenging profile, due to a variety of causes, including biochemical differences, genetics and/or co-morbidities, all of which factor into the medical management of drugs and biological products. Practitioners should have the opportunity to evaluate the appropriate use of a new drug or biological product and its effect on patient outcomes and interactions with other medications the patient is currently taking, with other co-morbidities, and with what is age-appropriate. Further, unlike the SCI criteria for the TPNIES, where biochemical differences in patients rarely have an impact, the question of whether one drug is more effective than another can be impacted by characteristics that vary across patients such as age, gender, race, genetic predisposition and comorbidities. Each patient's unique medical profile must be assessed by the patient's physician in determining the plan of care, and we believe that, rather than being too rigid and limiting investment in new therapies, using the NDA Classification Codes for purposes of determining TDAPA eligibility will help promote innovative therapies for the ESRD patient on dialysis and support ESRD facility uptake.

Comment: One drug manufacturer stated CMS should be cautious in taking any steps to judge the innovativeness of new renal dialysis drugs. Beyond the specific proposals to narrow the TDAPA eligibility, the company questioned whether CMS should be judging which drugs are or are not innovative. The company acknowledged CMS' desire to provide an objective basis to distinguish innovative from non-innovative renal dialysis service drugs, but asserted that

it could be outside our authority to judge innovativeness of new drugs, regardless of the standard employed. Such a step could contravene section 1801 of the Act, which prohibits the Medicare program from interfering in the practice of medicine. The commenter states that the choice of prescribing any drug, including a new ESRD drug, should be between a patient and his or her doctor. As an example, they noted the Part D program has exhibited continuously high beneficiary satisfaction and costs below estimates, but has explicit prohibitions on government involvement in setting any kind of formulary.

Response: We appreciate this comment and believe that in using the FDA NDA Classification Codes, we are not interfering in the practice of medicine. We are not dictating what drugs may or may not be used on what patients. Rather, all FDA-approved renal dialysis drugs and biological products are accessible to all ESRD patients for the treatment of ESRD. As noted previously, we believe FDA's NDA Classification Codes would provide an objective basis that we can use to distinguish innovative from noninnovative renal dialysis service drugs for eligibility for the TDAPA for renal dialysis drugs that are included in functional categories. Unlike Part D, we are not setting a formulary, and we do not prohibit accessibility of any FDA-approved drug that is indicated for an ESRD patient for renal dialysis services. What we are limiting is eligibility for the TDAPA for new renal dialysis drugs and biological products in existing ESRD PPS functional categories to truly innovative products. We continue to believe that practitioners and their patients should make treatment decisions collaboratively.

Comment: We received comments from 2 pharmaceutical companies and a few individuals regarding the exclusion of specific products from TDAPA eligibility and the more restrictive eligibility of new renal dialysis drugs and biological products in the CY 2020 ESRD PPS proposed rule from what was finalized in the CY 2019 ESRD PPS final rule, which included

all new renal dialysis drugs and biological products. A professional association, a drug manufacturer, a physician and an individual commenter urged CMS not to finalize the proposed changes to the TDAPA eligibility criteria under the CY 2020 ESRD PPS proposed rule, and to instead maintain the CY 2019 ESRD PPS final rule's expanded eligibility criteria for TDAPA, with an effective date of January 1, 2020. They stated that under our current proposal the TDAPA eligibility criteria would be too narrowed, resulting in ESRD facilities not having the opportunity to incorporate the many new and innovative drugs into their care plans and to make appropriate changes in their businesses to adopt such products.

They also commented that, compared to the TDAPA eligibility criteria finalized under the CY 2019 ESRD PPS final rule, the CY 2020 ESRD proposed rule has significant differences that affect what the stakeholders have been expecting, planning, relying upon and preparing for since the November 2018 publication of the CY 2019 ESRD PPS final rule. The commenter noted that those provisions currently are scheduled to take effect on January 1, 2020 and asserted that changing the TDAPA eligibility criteria would provide stakeholders with very little time between issuance of a final rule and the proposed effective date to plan for or adapt to any changes. The commenters stated that implementing such a significant change so quickly would be imprudent and unfair to ESRD stakeholders.

One drug manufacturer commented that NDA approval pathways, rather than NDA Classification Codes, are the clearest method for making TDAPA eligibility determinations for new renal dialysis drugs. The same drug manufacturer noted that for drug products, approval through FDA's statutory 505(b)(1) NDA pathway reflects a rigorous process used for new and novel drugs, and requires substantial clinical data and robust review. As such, drugs approved under the 505(b)(1) NDA pathway should be eligible for TDAPA. The drug manufacturer

opined that this is a clear standard anchored in statute and not subject to changes based in internal FDA policies and procedures created for administrative purposes.

In addition, the drug manufacturer noted that eligibility on the basis of NDA approval pathway allows clarity for stakeholders and reflects an appropriate balance between the goals CMS has articulated in the CY 2020 ESRD PPS proposed rule with respect to incentives for innovation and concerns regarding costs. The drug manufacturer suggested that CMS should maintain the TDAPA eligibility criteria finalized under the CY 2019 ESRD PPS final rule, which would apply the TDAPA to all new renal dialysis drugs or biological products approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the PHS Act, effective January 1, 2020. The drug manufacturer explained that basing the TDAPA eligibility criteria on NDA approval pathway also would be consistent with CMS regulations and policies in other contexts that refer to NDA approval pathways. For example, the Medicaid program has definitions for innovator drugs that focus on NDA approval pathways, and the CMS HCPCS Level II coding process involves considerations of FDA approval pathways (as well as certain FDA Orange Book designations), among other criteria. The commenter further noted that, if CMS does move forward with the proposed modifications, the changes should not go into effect until January 1, 2021. The commenter urged CMS to re-evaluate and revise both the substance of the proposed TDAPA eligibility changes, as well as the proposed effective date for any changes that may be finalized.

Response: Thank you for these comments. As discussed in the CY 2020 ESRD PPS proposed rule, we re-evaluated the expanded TDAPA policy in the CY 2019 ESRD PPS final rule based on numerous calls, correspondence, meetings and comments, requesting we narrow TDAPA eligibility, as well as based on our overall policy goals for the TDAPA and the financial

impact of those broad-reaching goals. As the TDAPA eligibility policy finalized in the CY 2019 ESRD PPS final rule had not been implemented yet, and as we evaluated our goal to support innovation and promote competition, while simultaneously being prudent with regard to Medicare spending, we weighed all aspects of the current and future risks in these areas and carefully made a decision to propose to narrow the CY 2019 ESRD PPS TDAPA eligibility policy in the most objective way possible. As noted previously, we are finalizing this proposal effective January 1, 2020. We do not believe postponing the implementation of this new policy to January 1, 2021 is necessary and we believe doing so would be operationally challenging.

With regard to using the FDA approval pathways to determine innovation, we found the use of only the 505(b)(1) pathway to be too narrow and the 505(b)(2) pathway to be too broad. The commenter mentioned using Medicaid's definition of innovator drugs, but that definition includes line extensions and generic drugs and we do not believe those drugs and biological products to be truly innovative for purposes of our TDAPA policy.

Comment: One commenter requested that CMS review every new FDA approved drug for dialysis.

Response: To date, only one type of renal dialysis drug (calcimimetics) has been eligible for the TDAPA. We anticipate that additional renal dialysis drugs and biological products will become eligible in the future and are exploring the potential use of application forms requesting specific information. Consistent with our current policy, we will review all requests submitted for the TDAPA.

We do not agree with the commenter that we should review every new FDA approved drug for dialysis. We believe that it is appropriate for us to use the process that we discussed in

the CY 2016 ESRD PPS final rule and on the CMS website[19] whereby after FDA approves drugs and biological products for use in ESRD patients, the products then go through a process to establish a billing code, that is, the HCPCS code process. When the HCPCS application is submitted and the drug manufacturer notifies us of its interest in eligibility for the TDAPA we then analyze the information in the FDA-approved labeling and the HCPCS application information, including studies submitted as part of these two standardized processes. This process provides an approach that facilitates a dialogue between the interested stakeholder and CMS creating a more robust forum for the evaluation of the eligibility for the drug or biological product for the TDAPA under the ESRD PPS.

Comment: One national dialysis association stated that CMS should remain open to future refinements of the TDAPA eligibility requirements, including the ability to make exceptions to these rules if a drug would be of significant clinical value for the treatment of ESRD. They asserted that the excluded NDA Classification Codes are a good place to start, but CMS should ensure that this policy is adjusted or that exceptions are granted, as needed.

Response: We appreciate the support and noted in our CY 2020 ESRD PPS proposed rule (84 FR 38346) that we would remain open to future refinements of the TDAPA eligibility requirements. Specifically, we said that based on our past experience and our expectation of detailed analysis of future drug product utilization, pricing and payment, CMS anticipates proposing further refinements to the TDAPA policy through notice and comment rulemaking in the future.

We received several comments from stakeholders specifically supporting the exclusion of generic drugs. The comments and our responses to the comments on our proposal to exclude

[19] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.

generic drugs are set forth below.

Comment: Some commenters supported our proposal to exclude drugs approved by FDA under section 505(j) of the FD&C and drugs for which the NDA types are for products that are not truly innovative. MedPAC and several other commenters supported the exclusion of generic drugs from TDAPA eligibility. However, they also stated CMS should exclude biosimilar biological products because they would be neither new nor innovative. MedPAC questioned our proposal that products that receive FDA approval under section 351 of the PHS Act, which occurs for new biological products and biological products that are biosimilar to, or interchangeable with, a reference biological product, would continue to be eligible for the TDAPA, even though we acknowledged that these products may not be innovative. MedPAC asserted that CMS should not pay more for a new technology without evidence that it improves outcomes for Medicare beneficiaries. One non-profit provider association recommended CMS revisit its assumptions and conclusions about biosimilar biological products in future rulemaking with the benefit of more experience.

Response: We thank commenters for the support regarding the exclusion of generic drugs reflected in ESRD PPS functional categories from eligibility for the TDAPA. CMS continues to support the development and the utilization of these products that contain innovative technology for the treatment of ESRD. As we discussed in the CY 2020 ESRD PPS proposed rule, the approval process for biosimilar biological products is a different pathway than that for generic drugs and has different requirements. We believe that a categorical exclusion from TDAPA eligibility for all biological products that are biosimilar to or interchangeable with a reference biological product, would disadvantage this sector of biological products in a space where we are trying to support technological innovation. While the products themselves may not

be innovative, CMS believes the technology used to develop the products is sufficiently new and innovative to warrant TDAPA payment at this time. However, unlike NDAs submitted pursuant to sections 505(b)(1) or 505(b)(2) of the FD&C Act, we do not have a categorical system to use as a proxy for assistance in determining which types of applications would meet the intent of the TDAPA policy. Therefore, we are finalizing our proposal to continue to allow all biosimilar to or interchangeable with a reference biological products to remain eligible for the TDAPA instead of proposing to exclude all of them.

However, as noted in the CY 2020 ESRD PPS proposed rule, we are aware that there are similar concerns about providing the TDAPA for these products that there are with generics, that increased drug class competition for biosimilar biological products did not translate into pricing reductions, and there was a market failure contributing to the rising costs of prescription drugs with the increases borne solely by Medicare. Therefore, we will monitor future costs of biosimilar biological products as they pertain to renal dialysis, the TDAPA, and the ESRD PPS, and we may revisit the recommendation to exclude biosimilar biological products from TDAPA eligibility in future rulemaking.

Comment: A few commenters asked about TDAPA eligibility for specific products and their placement in the ESRD PPS functional categories, and requested that CMS permit eligibility for the TDAPA for drugs within functional categories with a different mechanism of action. One commenter requested that CMS support FDA Breakthrough Therapy Designation products.

Response: Currently, we have established a TDAPA request process which is available on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html. We anticipate establishing a more

formal application process in the future as more new renal dialysis drugs and biological products become available. With regard to TDAPA eligibility for specific products, we would need to review the submitted TDAPA request to make that determination. We intend to provide further information regarding a TDAPA application process in the future.

Regarding the comment about FDA Breakthrough Therapy Designation products, this refers to a drug that is intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition and has preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is granted Breakthrough Therapy Designation by FDA, FDA will expedite the development and review of such a drug. The FDA does not announce when a drug has been granted Breakthrough Therapy Designation. It does not disclose information regarding sponsors who submitted requests for or who have been granted or denied Breakthrough Therapy Designation. Breakthrough Therapy Designation requests are typically submitted to an Investigational New Drug (IND), and the FDA cannot disclose the existence of an IND, or any submissions that have been submitted to the IND, unless it has previously been publicly disclosed or acknowledged per 21 CFR 312.130(a). The restrictions discussed previously create an issue for determining TDAPA eligibility since this information is not publicly available. To the extent a new renal dialysis drug or biological product is designated as a Breakthrough Therapy and otherwise meets the eligibility criteria for the TDAPA, it would be eligible for the add-on payment adjustment.

Comment: Numerous stakeholders requested that CMS increase the ESRD PPS base rate following any one of the following scenarios: at the end of the TDAPA eligibility period; when a

new drug is added to the ESRD PPS functional category; or, when a new product emerges within a functional category or composite rate that is of high clinical value to patients and is utilized by a significant number of beneficiaries with ESRD where there are simply not sufficient funds allocated within the ESRD PPS to cover the cost of the new drug. Counter to this, MedPAC asserted CMS should not make duplicative payments for a new product assigned to a functional category by providing the TDAPA for 2 years in addition to paying for its functional category under the ESRD PPS base rate. For example, MedPAC stated, the agency could reduce the TDAPA amount to reflect the amount already included in the ESRD PPS base rate. MedPAC noted that CMS should 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. MedPAC pointed out that CMS proposed a similar approach for the TPNIES. Some commenters suggested that CMS should apply funds not expended under the narrower TDAPA eligibility policy to make ESRD PPS adjustments when it adds new products to the ESRD PPS base rate. These commenters recommended that CMS establish a payment adjustment that equals the incremental difference between any amounts associated with the functional category currently in the base rate attributable to the new product's cost, which may result in CMS adding the product's full cost if the ESRD PPS base rate does not include any such reimbursement or a lesser amount that reflects current dollars in the ESRD PPS base rate.

Another commenter advocated that CMS create a non-budget neutral methodology to incorporate novel or improved technologies, including drugs and devices that will better the lives of patients with kidney failure, into the ESRD PPS bundled payment and that future novel products or technologies for treating patients with kidney failure will require different

reimbursement pathways than the PPS. This commenter stated there needs to be new money for innovative drugs and devices, and that a bundled payment works for drugs, devices, and care strategies that are used by the vast majority of patients at similar doses or that are inexpensive enough to be affordable within a highly capitated payment model. However, the commenter does not believe that a bundled payment works for drugs, devices, and care strategies that are both expensive and used by a minority of patients treated within the capitated payment model, particularly when the total number of patients within each payment unit are sufficiently small that one or 2 high utilizers will make a marked difference in margins.

Response: We appreciate the comments and suggestions of MedPAC and the many commenters regarding increasing the base rate in several scenarios, including making any additions to it in a non-budget neutral manner; reconciling the TDAPA with either what is already in the ESRD PPS base rate or with what is in each ESRD PPS functional category; making separate, non-PPS reimbursement pathways for new and innovative drugs, and fund-shifting from "would have been" expenditures under the TDAPA eligibility criteria finalized in the CY 2019 ESRD PPS final rule to adding those dollars to the base rate. As described previously, the comments ranged widely from adding the cost of all new renal dialysis drugs to the ESRD PPS base rate to only adding the difference to what is currently in the base rate, to still more fiscally conservative suggestions of netting out TDAPA expenditures with what is already in the base rate.

As we stated in the CY 2016 ESRD PPS final rule (80 FR 69016), we believe we have the authority to add new renal dialysis services to the bundle under both sections 1881(b)(14)(B) of the Act and 217(c)(2) of PAMA. First, we read section 1881(b)(14)(B)(iii) of the Act as requiring the inclusion of a specific category of drugs in the bundle—that is, drugs and

biologicals, 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 read 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 biologicals, 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''—to require us to both define and implement a drug designation process for including new injectable and IV products into the ESRD PPS bundled payment.

As we stated in the CY 2019 ESRD PPS final rule (84 FR 56935), we do not believe it would 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 rate whenever something new is made available. Additionally, the statute does not require that we add dollars to the ESRD PPS base rate when a new item is available. As we explained in that rule, the intent of the TDAPA for new renal dialysis drugs and biological products that fall within an ESRD PPS 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.

Through the legal levers available to us, we strive to not only support innovation and

competition for new renal dialysis drugs and biological products that fall within an ESRD PPS functional category, but also to align resource use with payment, while simultaneously balancing that payment with prudent spending of Medicare dollars. Medicare spending on prescription drugs continues to grow at rates far in excess of inflation, which poses challenges for both CMS and for providers seeking to give patients innovative therapies that can improve health outcomes and quality of life but at a cost that both patients and providers can afford.

Comment: One LDO requested that the drug designation process be patient centered and not increase patient expense for a new drug eligible for the TDAPA in which there is no clear evidence of an improvement in one or more patient-centered outcomes. The LDO stated that improvements in surrogate outcomes, such as laboratory values, is not sufficient. The LDO noted that if a new drug really improves patient-centered outcomes, the ESRD PPS base rate should be increased to pay for it after the 2 year TDAPA period regardless of whether the drug fits into a functional category. However, one national dialysis association referenced CMS' assertion that restricting TDAPA eligibility would reduce CY 2020 Medicare expenditures, which would have a favorable downstream impact on beneficiary co-insurance, and argued that patients are willing to accept higher cost sharing in exchange for any innovation in the ESRD space.

Response: We agree with the LDO that all treatment should be patient-centered, and encourage drug choices be made in discussion with the patient regarding potential improved outcomes weighed against additional out-of-pocket cost to the patient. We note that physicians are not obligated to prescribe a new drug for a dialysis patient if they do not feel it would yield improved clinical outcomes for the additional co-insurance obligation of the patient. For any new renal dialysis drug or biological product that meets the TDAPA eligibility criteria, the 20

percent co-insurance for those drugs is statutorily mandated on the ESRD PPS payment amount, which includes the amount for the TDAPA.

Final Rule Action: After consideration of public comments, for CY 2020, we are finalizing the revisions to the drug designation process regulation as proposed. That is, we are finalizing the proposed revisions to § 413.234 by revising paragraph (b)(1)(ii) and adding paragraph (e), effective January 1, 2020, to specify that a new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the TDAPA if it is a generic drug or if the NDA for the drug is classified by FDA as a certain type—specifically, if the drug is approved under section 505(j) of the FD&C Act or the NDA for the drug is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8.

We also proposed a technical change to § 413.234(a) to revise the definitions "ESRD PPS functional category" and "Oral-only drug" to be consistent with FDA nomenclature. We proposed to change the definition of "ESRD PPS functional category" to replace "biologicals" with "biological products." We also proposed to change the definition of "Oral-only drug" to replace "biological" with "biological product."

We did not receive any comments on our proposed technical changes to § 413.234(a) to revise the definitions. We are therefore finalizing these changes as proposed.

d. Modification of the Basis of Payment for the TDAPA for Calcimimetics in CY 2020

In the CY 2016 ESRD PPS final rule (80 FR 69025 through 69026), we finalized an exception to the drug designation process for calcimimetics. Specifically, we identified phosphate binders and calcimimetics as oral-only drugs and, in accordance with § 413.234(d), 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 FDA. We stated that under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category, so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and finalized in the CY 2016 ESRD PPS final rule that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the base rate to account for these drugs. We further stated that we intend to use notice-and-comment rulemaking to include the oral and non-oral forms of calcimimetics and phosphate binders in the ESRD PPS bundled payment after the payment of the TDAPA. We explained that when these drugs are no longer oral-only drugs, we will pay for them under the ESRD PPS using the TDAPA based on the payment methodologies in section 1847A of the Act for a period of at least 2 years.

Change Request 10065, Transmittal 1889 issued August 4, 2017, replaced by Transmittal 1999 issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018. As discussed previously, calcimimetics will be paid using the TDAPA for a minimum of 2 years until sufficient claims data for rate setting analysis is available for these products. Since payments have been made beginning January 1, 2018, a 2-year period would end December 31, 2019. We are still in the process of collecting utilization claims data for both the oral and non-oral form of calcimimetics, which will be used for a rate setting analysis. Therefore, in the CY 2020 ESRD PPS proposed rule, we stated that we will continue to pay for

calcimimetics using the TDAPA in CY 2020 (84 FR 38347).

We also discussed in the proposed rule that in the CY 2019 ESRD PPS final rule (83 FR 56943), we stated that we would continue to pay the TDAPA using the pricing methodologies under section 1847A of the Act (which includes ASP+6 percent) until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. We noted that calcimimetics were the first drugs for which we paid the TDAPA (83 FR 56931), and increased Medicare expenditures by $1.2 billion in CY 2018. It is clear, therefore, that ESRD facilities are furnishing these innovative drugs. We explained in the CY 2019 ESRD PPS final rule (83 FR 56943) that one of the rationales for the 6 percent add-on to ASP has been to cover administrative and overhead costs. We also explained that the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56944).

As we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38347), we have provided the TDAPA for calcimimetics for 2-full years, and we believe that is sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. Therefore, we proposed that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, would be 100 percent of ASP. That is, we proposed to modify § 413.234(c) by removing the clause "except that for calcimimetics it is based on the pricing methodologies under section 1847A of the Social Security Act." We stated that we believed this proposal strikes a balance between supporting ESRD facilities in their uptake of these products and limiting the financial burden that increased payments place on beneficiaries and Medicare expenditures. We also noted that this policy would be consistent with the policy finalized for all other new renal dialysis drugs and biological products in the CY

2019 ESRD PPS final rule (83 FR 56948).

In addition, we noted that our proposal to condition the application of the TDAPA on CMS's receipt of ASP data, discussed in section II.B.2.c of this final rule, would also apply with respect to calcimimetic products.

The public comments and our responses to the comments regarding our proposal to change the basis of payment for the TDAPA for calcimimetics are set forth below.

Comment: MedPAC supported the proposal and stated that there is good rationale to change the basis for the TDAPA from ASP plus 6 percent to ASP with no percentage add-on. MedPAC noted that the ASP plus 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 ESRD 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 ESRD facilities. If the intent of the "+6 percent" was to address acquisition price variation, MedPAC asserted that rationale is diminished for ESRD facilities. Second, MedPAC noted that the TDAPA is an add-on payment adjustment to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of renal dialysis drugs and biological products. Therefore, if the intent of the "+6 percent" was to address storage and administration costs, MedPAC believed these costs are already addressed through the ESRD PPS bundled payment and thus do not warrant the additional 6 percent.

A national dialysis association disagreed with MedPAC regarding ASP+6 in the ESRD

facility setting. The commenter stated that while ASP+6 is used in physician reimbursement, it is also used across the Medicare program as the reimbursement standard for health care providers of all types, including providers that are much larger than ESRD facilities, such as large hospital systems. This commenter, along with another commenter, expressed that recommending that ESRD facilities be paid differently than other health care providers for the same pharmaceutical products runs counter to MedPAC's longstanding view that Medicare should pay similar rates for similar care.

A drug manufacturer and an LDO expressed similar beliefs as the national dialysis association, stating that CMS should maintain parity in reimbursement across other settings of care in which ASP-based reimbursement is provided at ASP plus 6 percent. One commenter noted that the 6 percent add-on is important for patient access in ESRD facilities, like other health care providers. The other commenter noted that other Medicare payment systems provide dispensing fees to recognize such costs, and the commenter believes ESRD facilities should be compensated for these costs as well.

An LDO and a drug manufacturer were disappointed with CMS' proposal to decrease the TDAPA for calcimimetics from ASP+6 to ASP+0. They noted that not all ESRD facilities can purchase a drug at the ASP and stated that this is particularly the case with calcimimetics. They also expressed concern that other policies, including the budget sequester, the 20 percent co-insurance exclusion from bad debt, and unpaid cost-sharing obligations by states, will result in TDAPA payments for calcimimetics far below the ASP. One association stated that cutting the TDAPA reimbursement for calcimimetics to ASP+0 would actually move the baseline reimbursement to, at best, ASP-1.6 after application of the ongoing sequester.

A national dialysis stakeholder organization stated that given the amount of money

attributed to the ESRD PPS functional categories other than anemia management, it is difficult to see how any dollars could be used to cover the administrative costs of calcimimetics or any other products. A drug manufacturer and a national dialysis organization noted that ESRD facilities, like other providers of Part B- covered drugs, rely on the 6 percent add-on to help cover the costs of acquiring and handling drugs, and in the case of the oral form of the calcimimetic, dispensing the drug.

Another commenter explained that ESRD facilities need the current 6 percent add-on amount to help pay for the expensive storage, packaging, and administration costs associated with products eligible for the TDAPA (which require facilities to ensure registered nurses are available because they administer calcimimetics to patients). For example, such costs include: shipping medications to the patient's home, particularly for homecare and nursing home patients; pharmacy dispensing fees, especially in the case of the many small providers that do not have pharmacy licenses; storage and utility costs to account for the drug's refrigeration requirement; purchasing costs; rinse back procedures, which require a registered nurse and the facility ensuring that a registered nurse is on-site; pill usage accounting; and billing procedures and processes, among others. The commenter explained that these costs are especially challenging for small and independent providers to bear when considering the fact that they also generally experience less favorable drug acquisition pricing than LDOs with significant market advantage and negotiating power.

An LDO explained that it continues to face significant administrative and overhead costs resulting from the inclusion of the calcimimetics into the ESRD PPS via the TDAPA. The commenter stated that these costs not transitional as CMS asserts. The commenter explained that it incurs ongoing costs for staff training on clinical protocols as well as costs related to internal

updates for clinical and financial systems. A national dialysis association provided similar comments, stating the operational costs associated with furnishing calcimimetics to ESRD beneficiaries, such as storing, handling, and dispensing the drugs, are ongoing for so long as the drugs are furnished under the ESRD PPS and that there is no mechanism through which ESRD facilities can address these costs without reimbursement.

A home dialysis association expressed concern regarding the ESRD facility costs associated with home dialysis patients. The commenter noted that according to their members, approximately 25 percent of patients, both home and in-center, take some form of calcimimetic drug. The commenter explained that for home dialysis patients, the costs associated with actually getting the drug to the patient is especially important given that they are not present in clinic as often as in-center patients. The commenter stated that ESRD facilities must spend considerable time and resources making certain that these patients have access to necessary medications, like calcimimetics. Two commenters stated that CMS made a commitment in the CY 2016 ESRD PPS final rule, and reiterated that commitment in subsequent rulemaking, that it would reimburse the TDAPA using the pricing methodologies under section 1847 of the Act, which includes ASP+6 percent, until sufficient claims data for rate setting analysis are available, but not for less than 2 years. The commenters noted CMS should maintain this commitment to pay the TDAPA for calcimimetics at ASP+6 percent for the duration of the TDAPA period.

Response: The TDAPA is an add-on payment adjustment under the ESRD PPS, and is not intended to be a mechanism to make separate payment for Part B drugs. Section 1842(o) of the Act, which specifies payment for drugs included in a physician's or supplier's bill that are not paid on a cost or prospective payment basis as otherwise provided under Part B, provides for payment using the methodologies under section 1847A of the Act. In our CY 2019 ESRD PPS

final rule(83 FR 56948), we stated that ASP +0 would be the basis for the TDAPA prospectively for all new renal dialysis drugs and biological products effective January 1, 2020. We explained that calcimimetics were excluded from this policy and the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We also 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 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 among 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 co-insurance) and stakeholder concerns, including those about incentivizing use of high cost drugs in ESRD facilities.

We believe that we have flexibility under section 1881(b)(14)(D)(iv) of the Act to base the amount of the TDAPA on a methodology that is not based on a payment methodology under section 1847A of the Act. There is no requirement to use the payment methodologies under section 1847A of the Act for renal dialysis drugs under the ESRD PPS. As a result we have reconsidered the use of the ASP+6 percent methodology under section 1847A of the Act for the TDAPA for calcimimetics and proposed to use ASP+0 instead.

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 an add-on payment adjustment to the ESRD PPS base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. We appreciate MedPAC's support for this proposal and agree that ASP +0 is appropriate as the basis for the TDAPA for calcimimetics for CY 2020. For all of these reasons, we are finalizing the proposal without modification.

Comment: Some commenters explained that the ASP does not reflect the cost of many ESRD facilities who purchase products well above the ASP. An LDO noted that not all ESRD facilities can purchase a drug at the ASP and that this is particularly the case with calcimimetics. A drug manufacturer explained that the ASP is a market-based price that reflects the weighted average of all manufacturer sales prices and includes most rebates and discounts that are negotiated between manufacturers and purchasers in the commercial market. The manufacturer explained that not all health care providers receive the same discounts, therefore the manufacturer believes that the 6 percent add-on is important in ensuring patient access across providers. The commenter further explained that discounts provided to the supply chain – such as wholesalers – may be included in the ASP but may not be passed on to ESRD facilities.

Response: We understand the concerns expressed by the commenters about ASP, and the difficulties that may be encountered by small dialysis centers unable to negotiate the lower drug prices attributed to volume, and inaccessibility to supply chain discounts. The purpose of the TDAPA policy is not to offset business losses or to enhance business profits. The TDAPA is an add-on payment adjustment under the ESRD PPS, and is not intended to be a mechanism to make separate payment for Part B drugs. Section 1842(o) of the Act, which specifies payment for drugs included in a physician's or supplier's bill that are not paid on a cost or prospective payment basis as otherwise provided under Part B provides for payment using the methodologies

under section 1847A of the Act. We do, however, continue to believe ASP data is the best data available for the purposes of determining the basis of payment for the TDAPA since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions. With regard to the importance of the six percent add-on, we continue to 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.

Comment: Some commenters expressed concern that our proposal to base the TDAPA payments for calcimimetics at 100 percent of ASP for CY 2020 could jeopardize patient access to calcimimetics and have unintended consequences. One commenter stated that this would particularly affect patients treated by small and independent providers often in rural and underserved areas with limited resources and low to negative Medicare margins. A drug manufacturer commented that basing the TDAPA on ASP +0 would disincentivize the adoption of innovative new therapies and that policies designed to facilitate patient access to innovative new therapies should not reduce the add-on payment to the ASP that ensures providers are able to deliver these medicines to patients.

An LDO expressed concern that ESRD facilities will be forced to choose between ceasing to provide the calcimimetics or losing additional money every time they provide calcimimetics. The LDO also expressed concern that the proposal could inhibit generic drug adoption and encourage utilization of the branded IV calcimimetic at great expense to the Medicare program and its beneficiaries. The LDO stated that it is committed to providing

patients with the most cost-effective option for treatment, which typically results in prioritizing oral generic drugs and reserving the IV option for patients who otherwise fail to respond to treatment on the oral form. However the LDO strongly urged CMS to consider that, at ASP +0, many providers will lose money on cinacalcet, which could incentivize a shift in first line treatment to the IV version at a much greater cost to the program. A national dialysis association expressed similar concerns, stating that the proposal could incentivize use of the IV calcimimetic over the generic oral calcimimetic as ESRD facilities grapple with choosing the product for which they will lose the least amount of money due to declining reimbursement.

An LDO expressed concern that shifting the basis of payment in the middle of the TDAPA period for calcimimetics could skew the utilization and claims data used to inform post-TDAPA payment and that CMS should continue payment at 106 percent of ASP during the third year of TDAPA to ensure payment adequacy and consistency in utilization data it is collecting.

Response: As noted previously, 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. We further 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. Regarding the concern that reducing the basis of TDAPA payment to ASP+0 for calcimimetics will steer ESRD facilities toward not providing the drug, or toward providing an alternative form of the drug, we believe that physicians and their patients should make the decision together on the appropriate form of the drug for treatment. It is not our intent to interfere with that decision making process.

As the number of drugs within each functional group increases and market share competition from the manufacturers is a factor, we anticipate easier access, more choices in care and lower prices. We acknowledge that payment policies may have unintended consequences as identified by the commenters, however, it is our expectation that ESRD facilities will follow the physician's plan of care for the patient and we will closely monitor drug utilization at the beneficiary and facility level for these types of issues.

With respect to the concern that reducing the basis of payment to ASP+0 for calcimimetics will complicate the data we will use when considering whether to modify the base rate at the end of the TDAPA period, we are currently evaluating potential methodologies for this purpose. There are a number options being discussed as a result of stakeholder input and at the time we undergo rulemaking, we will analyze the data available and input received from stakeholders when developing our proposal to incorporate these products into the ESRD PPS base rate.

Comment: Several commenters stated that CMS has indicated in previous rules that the ESRD PPS base rate does not include administrative costs associated with dispensing oral drugs. One commenter noted in addition to the small dollar amounts allocated to drugs in most ESRD PPS functional categories, CMS has stated that the base rate does not include the cost of oral-only drugs. Another commenter stated that while CMS indicates that the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products, this statement contradicts CMS' earlier statement regarding calcimimetics that dollars were never included in the base rate to account for these drugs. The commenter noted that CMS acknowledged there are no dollars in the base rate for calcimimetics and therefore cannot assert that there are dollars in the base rate available to cover administration and overhead related to

calcimimetics.

Response: As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56944 through 56946), 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 pointed out that under the current ESRD PPS, new renal dialysis drugs that are considered to be in a functional category would 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. There is no clear reason for the 6 percent add-on, and, as MedPAC discussed in its June 2015 report, there is no consensus among stakeholders on the purpose of the 6 percent add-on. 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 co-insurance) and stakeholder concerns discussed in section II.B.1.e of the CY 2019 ESRD PPS final rule. We note that since January 1, 2018, ESRD facilities have been receiving the TDAPA for calcimimetics at ASP+6 as part of the ESRD PPS payment amount. We continue to believe that 2 full years of paying the TDAPA at ASP+6 is sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics.

Comment: A national dialysis association explained that its review of the publicly available data on Medicare's spending on calcimimetics indicates that Medicare spending has decreased under the TDAPA as compared to prior payment policies. The commenter explained that in CY 2017, prior to CMS moving calcimimetics from Medicare Part D to the ESRD PPS

under Part B, CMS spent more than $1.4 billion on calcimimetics. Between 2013 and 2017, the price per unit of calcimimetics increased by an average of 15 percent each year, compared to an average increase in patients utilizing calcimimetics of 6 percent each year. The commenter asserted that had these trends continued, CMS would have paid almost $1.8 billion for calcimimetics in Part D in CY 2018. The commenter acknowledged that the Part D data set includes all beneficiaries using calcimimetics and not just those with ESRD, but noted that majority of beneficiaries using calcimimetics are ESRD beneficiaries. The commenter stated that it cannot identify a data source that supports CMS' claim of a $1.2 billion increase in Medicare spending on calcimimetics in CY 2018. On the contrary, the commenter's review of the data indicates that Medicare spending on calcimimetics decreased under the TDAPA from more than $1.4 billion in CY 2017 to $1 billion represented in the file containing 85 percent of the claims in CY 2018. The commenter believes that that because calcimimetics moved from Part D spending to Part B spending in CY 2018, that CMS should not claim an increase in Part B spending. The commenter stated that if there is another source of data that the public should review in order to fully evaluate CMS' claims, then that data should be made available along with the rulemaking. The commenter further asserted that if CMS's statement of an increase in Medicare spending on calcimimetics is not correct or corroborated by the data, it is not adequate justification for the proposal to change reimbursement for the TDAPA for calcimimetics from ASP+6 to ASP+0 and CMS should not finalize this proposal.

Response: In response to the commenter's questions about the $1.2 billion increase in Medicare costs for calcimimetics, we clarify that the $1.2 billion figure refers to expenditures under the ESRD PPS for CY 2018, as reflected in claims, due to the utilization of calcimimetics alone.

We do not believe that it is appropriate to consider expenditures in other Medicare or Medicaid funding areas when developing policies under the ESRD PPS. These funding areas are not co-mingled or mutually interchangeable. In addition, the Part B spending includes the injectable form of the calcimimetic which was not covered under Part D. We have further reviewed our data for CY 2018 and stand by the stated 1.2 billion increase to ESRD PPS expenditures.

Final Rule Action: After careful consideration of public comments, we are finalizing our proposal that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, will be 100 percent of ASP. Specifically, we are finalizing the proposed modification to § 413.234(c) by removing the clause "except that for calcimimetics it is based on pricing methodologies under section 1847A of the Social Security Act."

e. Revision to 42 CFR 413.230

In the CY 2011 ESRD PPS final rule (75 FR 49200), we added § 413.230 to 42 CFR part 413, subpart H to codify that the per treatment payment amount is the sum of the per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235; any outlier payment under § 413.237; and any training adjustment add-on under § 414.335(b). The per treatment payment amount is Medicare's payment to ESRD facilities under the ESRD PPS for furnishing renal dialysis services to Medicare ESRD beneficiaries.

In the CY 2016 ESRD PPS final rule (80 FR 69024), we codified the drug designation process regulation in § 413.234, which provides a TDAPA under § 413.234(c) when certain eligibility criteria are met. We apply the TDAPA at the end of the calculation of the ESRD PPS payment, which is similar to the application of the outlier payment (§ 413.237(c)) and the

training add-on adjustment (§ 413.235(c)). That is, once the ESRD PPS base rate is adjusted by any applicable patient- and facility-level adjustments we add to it any applicable outlier payment, training add-on adjustment, or TDAPA.

In CY 2016 ESRD PPS rulemaking, we did not propose a corresponding revision to § 413.230 to reflect that the TDAPA is a component in the determination of the per treatment payment amount. Therefore, in the CY 2020 ESRD PPS proposed rule (84 FR 38347), we proposed a revision to § 413.230 to add paragraph (d) to reflect the TDAPA. We stated that we believed this modification is necessary so that the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount. We noted that this revision to the regulation would not change how the ESRD PPS per treatment payment amount is currently calculated. We also proposed to revise § 413.230 to include, as part of the calculation of the per treatment payment amount, any TPNIES as discussed in section II.B.3.b.iii of this final rule.

We also proposed a technical change to § 413.230(c) to replace "§ 414.335(b)" with a more appropriate reference to the training adjustment add-on requirement, which is "§ 413.235(c)." In the CY 2011 ESRD PPS final rule (75 FR 49202) we inadvertently referred to § 414.335(b), which states, "After January 1, 2011, a home and self-training amount is added to the per treatment base rate for adult and pediatric patients as defined in § 413.230" when finalizing § 413.230. Section 413.235(c) similarly states "CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training." However, as we explained in the CY 2020 ESRD PPS proposed rule, § 414.335(b) describes the training adjustment add-on when erythropoietin (EPO) is furnished to home dialysis patients, whereas § 413.235(c) describes the application of the training adjustment add-on more generally, even when EPO is not furnished. When we finalized § 413.230 in the CY 2011 ESRD PPS final rule, we intended for the training

adjustment add-on to apply more generally, not just when EPO is furnished, and therefore we are proposing to refer to § 413.235(c).

We did not receive any comments on our proposal for technical changes to § 413.230. Therefore, we are finalizing the changes as proposed.

2. Average Sales Price (ASP) Conditional Policy for the TDAPA

a. Background

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 a payment methodology for certain drugs and biological products not paid on a cost or prospective payment basis furnished on or after January 1, 2005. Payments made under this methodology are primarily based on quarterly data submitted to CMS by drug manufacturers, and most payments under this methodology are based on the ASP. ASP-based payments are determined from manufacturer's sales to all purchasers (with certain exceptions) net of 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. ASP-based payments are determined for individual HCPCS codes. To allow time for manufacturers to submit quarterly data and for CMS to determine, check and disseminate payment limits to contractors that pay claims, the ASP-based payment limits are subject to a 2 quarter lag, which means that sales from January to March are used to determine payment limits

in effect from July to September.[20]

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the drug products included in the HCPCS code. Section 1847A(b)(1)(B) of the Act also requires that the Medicare payment 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 (83 FR 56929). The WAC is defined in section 1847A(c)(6)(B) of the Act as the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Section 1847A(c)(4) of the Act further provides a payment methodology in cases where the ASP during 1st quarter of sales is unavailable, stating that in the case of a drug or biologicals during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological product are not sufficiently available from the manufacturer to compute an ASP for the biological product, the Secretary may determine the amount payable under this section for the drug or biological product based on the WAC or the methodologies in effect under Medicare Part B on November 1, 2003, to determine payment amounts for drugs or biological products. For further guidance on how Medicare Part B pays for certain drugs and biological products, see Medicare Claims Processing Manual (Pub. L. 100-04) (chapter 17, section 20) (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf).

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20 ASPE. Issue Brief. Medicare Part B Drugs: Pricing and Incentives. March 2016. Available at: https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf

We have used the payment methodology under section 1847A of the Act 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 (82 FR 50742 through 50743). In the CY 2016 ESRD PPS final rule (80 FR 69024), we adopted § 413.234(c), which requires that the TDAPA is based on payment methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such payment methodologies for Part B ESRD related drugs or biological products that qualify as an outlier service (82 FR 50745). For the purposes of the ESRD PPS, we use "payment methodology" interchangeably with "pricing methodology."

In the CY 2019 ESRD PPS final rule (83 FR 56948) we finalized a revision to § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to base the TDAPA on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We also explained in the CY 2019 ESRD PPS final rule (83 FR 56944) 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 from the manufacturer to compute an ASP. Therefore, we finalized a change to § 413.234(c) to specify that if ASP is not available, the TDAPA is based on 100 percent of WAC (WAC+0) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. We also modified § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). We specified that these changes to § 413.234(c) would be effective January 1, 2020.

In the CY 2019 ESRD PPS final rule (83 FR 56943), we discussed that 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. We further explained that we believe it may not be appropriate under section 1881(b)(14)(D)(iv) of the Act to base the TDAPA strictly on the pricing methodologies under section 1847A of the Act. We explained that, in the CY 2019 ESRD PPS proposed rule (83 FR 34315), we considered options on which to base payment under the TDAPA, for example, maintaining the policy as is or potentially basing payments on the facility cost of acquiring drugs and biological products. We found that while the pricing methodologies under 1847A of the Act, and specifically ASP, could encourage certain unintended consequences, ASP data continues to be the best data available since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions (83 FR 34315).

b. Basis for Conditioning the TDAPA on the Availability of ASP Data

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38348), under the change to § 413.234(c) finalized in the CY 2019 ESRD PPS final rule (83 FR 56948), effective January 1, 2020, the basis of payment for the TDAPA is ASP+0, but if ASP is not available, then it is WAC+0, and if WAC is not available, then it is based on the drug manufacturer's invoice. In the CY 2019 ESRD PPS final rule, we also modified § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6). As discussed in section II.B.1.d of the CY 2020 ESRD PPS proposed rule (84 FR 38330) and section II.B.1.d of this final rule, we proposed to modify the basis of payment for the TDAPA for calcimimetics for CY 2020 to ASP+0.

In the CY 2020 ESRD PPS proposed rule (84 FR 38348 through 38349), we discussed that, following publication of the CY 2019 ESRD PPS final rule, we continued to assess our policy allowing for WAC or invoice pricing if ASP is not available, and became concerned that it could lead to drug manufacturers who are not otherwise required to submit ASP data to CMS to delay submission or withhold ASP data from CMS so that ESRD facilities would receive a higher basis of payment for the TDAPA and be incentivized to purchase drugs from those manufacturers.

We stated that calcimimetics were the first drugs for which we paid the TDAPA (83 FR 56931), and this increased Medicare expenditures by $1.2 billion in CY 2018. We noted that the TDAPA for one form of the calcimimetics was based on WAC for 2 quarters, and was more expensive than ASP. In addition, there were delays in the submission of ASP data for that drug, but we are now receiving ASP data for both calcimimetics. We explained that we were concerned about the significant increase in Medicare expenditures that resulted from paying the TDAPA for calcimimetics, and about this trend continuing with new renal dialysis drugs and biological products that become eligible for the TDAPA in the future. We therefore believed we needed to limit the use of WAC (or invoice pricing) as the basis of the TDAPA to as few quarters as practicable to help limit increases to Medicare expenditures while maintaining our goals for the TDAPA policy—namely, supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products for those products that fall within a functional category and providing a pathway towards a potential base rate modification for those products that do not fall within a functional category.

We also noted that we were concerned that ASP will not be made available to CMS by drug manufacturers not currently required by statute to do so. Drug manufacturers who have

Medicaid Drug Rebate Agreements as part of the Medicaid Drug Rebate Program are required by section 1927(b)(3) of the Act to submit ASP sales data into CMS quarterly. However, we anticipated there could be drugs marketed in the future that are eligible for the TDAPA, but may not be associated with ASP reporting requirements under section 1927(b) of the Act. While manufacturers that do not have Medicaid Drug Rebate Agreements may voluntarily submit ASP data into CMS,[21] we stated that we were concerned manufacturers may not elect to do so. MedPAC and the Office of the Inspector General (OIG) have both noted concerns about manufacturers not reporting ASP data for Part B drugs. As discussed in MedPAC's June 2017 Report to Congress,[22] the OIG found that for the 3rd quarter of 2012, out of 45 drug manufacturers who were not required to submit ASP for Part B drugs, only 22 voluntarily submitted ASP data.[23]

We pointed out that even for those drug manufacturers who are required to submit ASP data into CMS, not all may fully comply. For the same 3rd quarter of 2012, the OIG found that at least 74 out of the 207 drug manufacturers with Medicaid Drug Rebate Agreements in place did not submit all of their required ASP data for their Part B drugs.[24] MedPAC's recommendations in its June 2017 report[25] would require that all Part B drug manufacturers submit ASP data into CMS, whether or not those manufacturers have a Medicaid Drug Rebate Agreement. Based on this data and our own experience with the calcimimetics, we expressed concern that

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21 MedPAC. Part B Drugs Payment Systems. October 2017. Page 2. Available at: http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0
22 Report to Congress, MedPAC, June 2017, page 42. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf
23 Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, Office of the Inspector General, page 7. Available at: https://oig.hhs.gov/oei/reports/oei-12-13-00040.pdf
24 Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs, Office of the Inspector General, pages 7-8, Available at: https://oig.hhs.gov/oei/reports/oei-12-13-00040.pdf.
25 Report to Congress, MedPAC, June 2017, pages 10-12. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf

manufacturers may not voluntarily report ASP data into CMS. We noted that we continue to believe that ASP is the best data currently available for the basis of payment for the TDAPA, because it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions (83 FR 56943). Therefore, we stated that we believed conditioning the TDAPA on the availability of ASP data is appropriate and necessary to ensure that we are basing the amount of the TDAPA on the best data available.

We noted in the CY 2020 ESRD PPS proposed rule (84 FR 38349) that, in addition to our concerns about ASP data reporting generally, we were concerned that the TDAPA policy finalized in the CY 2019 ESRD PPS final rule effective January 1, 2020, could potentially incentivize drug manufacturers who do not have a Medicaid Drug Rebate Agreement to delay or to never submit ASP data in order for ESRD facilities to receive an increased TDAPA for their products. As noted in section II.B.2.a of the CY 2020 ESRD PPS proposed rule, under § 413.234(c), effective January 1, 2020, if ASP is not available to CMS, the basis of payment for the TDAPA is WAC+0 and when WAC is not available, then the TDAPA is based on invoice pricing. As MedPAC discussed in its June 2017 Report to Congress, WAC-based payments would likely increase Medicare expenditures as compared to ASP-based payments. As stated in section 1847A(c)(5) of the Act, ASP is calculated to include discounts and rebates. WAC is ultimately controlled by the manufacturer, and its statutory definition in section 1847A(c)(6)(B) of the Act does not include the discounts that ASP includes.[26] Similarly, invoice pricing may not reliably capture all available discounts and thus may be inflated. This means if a drug manufacturer chooses not to submit ASP data into CMS, the TDAPA would be based on an

26 MedPAC. Part B Drugs Payment Systems. October 2017. Pages 43-44. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf,

inflated amount beyond what the average cost to ESRD facilities to acquire those drugs. This additional amount would also then increase the co-insurance for the beneficiaries who receive those drugs. We explained in the CY 2020 ESRD PPS proposed rule that we believed conditioning the TDAPA on the availability of ASP data is necessary to mitigate this potential incentive and limit increases to Medicare expenditures.

c. Proposal to Condition the TDAPA Application on the Availability of ASP Data

In the CY 2020 ESRD PPS proposed rule (84 FR 38349), we proposed to revise § 413.234(c) to address the following concerns: (1) increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for the TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS. Under our proposed revisions, we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin paying the TDAPA for the product. We noted in the CY 2020 ESRD PPS proposed rule that we were not proposing to modify the current ASP reporting process[27] and our proposals were consistent with this process. Since it is possible for a drug manufacturer to begin sales of its product in the middle of a calendar quarter, it may take approximately 2 to 3 quarters for CMS to obtain a full calendar quarter of ASP data. We explained in the CY 2020 ESRD PPS proposed rule that we believed that 3-calendar quarters is a reasonable amount of time for drug manufacturers to submit a full calendar quarter of ASP data to CMS; therefore, we proposed to allow 3-calendar quarters for drug manufacturers to make ASP available to CMS to enable ESRD facilities to continue to receive the TDAPA for a product.

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27 CMS. Medicare Part B Drug Average Sales Price. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html

As we discussed in section II.B.2.a of the CY 2020 ESRD PPS proposed rule, there is a 2 quarter lag between the sales period for which ASP is reported and the effective date of the rate based on that ASP data. During this period between when the TDAPA is initiated for a product and the effective date of the rate based on the full quarter of ASP data made available to CMS, consistent with the policy finalized in the CY 2019 ESRD PPS final rule (83 FR 56948), the basis of the TDAPA would be WAC+0, and if WAC is not available, then invoice pricing. Once the drug manufacturer begins submitting ASP data, the basis of the TDAPA would be ASP+0. We proposed that if we have not received a full calendar quarter of ASP data for a new renal dialysis drug or biological product by 30 days after the last day of the 3rd calendar quarter of applying the TDAPA for that product, we would stop applying the TDAPA within the next 2-calendar quarters. For example, if we begin applying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data for that product has not been made available to CMS by October 30, 2021 (30 days after the last day of the 3rd quarter of paying the TDAPA), we would stop applying the TDAPA for that product no later than March 31, 2022 (2 quarters after the 3rd quarter of paying the TDAPA).

We therefore proposed to revise the regulatory text at § 413.234(c) to provide that, notwithstanding the time periods for payment of the TDAPA specified in paragraphs (c)(1) and (c)(2), we would no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS has not received a full calendar quarter of ASP data for the product within 30 days after the last day of the 3rd calendar quarter after the TDAPA is initiated for the product.

We noted in the CY 2020 ESRD PPS proposed rule that we expect that once drug manufacturers begin submitting ASP data into CMS, they would continue to do so for the duration of the TDAPA period as set forth in § 413.234(c). We explained that we continue to

believe that basing the TDAPA on ASP+0, as compared to WAC+0 or invoice pricing, is the most appropriate choice for the ESRD PPS, and strikes the right balance of supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products and limiting increases to Medicare expenditures. We stated that if drug manufacturers were to stop submitting full quarters of ASP data for products that are eligible for the TDAPA, and we had to revert to basing the TDAPA on WAC or invoice pricing, we believed we would be overpaying for the TDAPA for those products.

Therefore, we also proposed to revise the regulatory text at § 413.234(c) to state that we would no longer apply the TDAPA for a new renal dialysis drug or biological product if a drug manufacturer submits a full calendar quarter of ASP data into CMS within 30 days after the close last day of the 3rd calendar quarter after the TDAPA is initiated for the product, but at a later point during the applicable TDAPA period specified in § 413.234(c)(1) or (c)(2), stops submitting a full calendar quarter of ASP data into CMS. We explained that we assess pricing for new renal dialysis drugs and biological products eligible for the TDAPA on a quarterly basis. Under our proposal, once we determine that the latest full calendar quarter of ASP is not available, we would stop applying the TDAPA for the new renal dialysis drug or biological product within the next 2-calendar quarters. For example, if we begin paying the TDAPA on January 1, 2021 for an eligible new renal dialysis drug or biological product, and a full calendar quarter of ASP data is made available to CMS by October 30, 2021 (30 days after the close of the 3rd quarter of paying the TDAPA), but a full calendar quarter of ASP data is not made available to CMS as of January 30, 2022 (30 days after the close of the 4th quarter of paying the TDAPA), we would stop applying the TDAPA for the product no later than June 30, 2022 (2 quarters after the 4th quarter of paying the TDAPA).

The comments and our responses to the comments on our proposal to implement an ASP conditional policy for application of the TDAPA are set forth below.

Comment: Several commenters stated that it is unfair to impose this condition on the TDAPA because it would reduce the payment amount provided to ESRD facilities, while it is the manufacturers who are responsible for submitting the ASP data into CMS. One LDO noted that ESRD facilities have no ability to influence whether a manufacturer submits ASP data into CMS, while another LDO further argued that CMS does not have the authority to impose this condition on the TDAPA since the facilities do not have control over whether the ASP data is submitted into CMS by the manufacturer.

Response: We have authority under section 1881(b)(14)(D)(iv) of the Act to include under the ESRD PPS such other payment adjustments as the Secretary determines appropriate, and we established the TDAPA for new renal dialysis drugs and biological products under this authority. We also have authority to place conditions on those payment adjustments, as we have otherwise done for the TDAPA by requiring that the renal dialysis drug or biological product meet certain eligibility criteria under § 413.234. As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38349), we are concerned about (1) increases to Medicare expenditures due to the TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for products eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS. We believe conditioning the TDAPA on the availability of ASP data is appropriate and necessary to address these concerns and ensure that we are basing the amount of the TDAPA on the best data available to address these concerns, and not overpaying through WAC or invoice pricing. In addition, we do not believe that this policy is unfair because we believe that ESRD facilities have the ability to influence drug

manufacturers to submit ASP data due to the manufacturers' desire to have market share. With more choices available through the ESRD PPS functional categories, drug manufacturers may want to retain or capture more market share with their products as competition increases. ESRD facilities are able to have discussions with drug manufacturers as to whether they reported the ASP into CMS and, if not, when they plan to do so.

Comment: A drug manufacturer and an LDO stated that we should only apply this policy on an individual basis, that is, if a drug is multi-source, meaning available from a brand-name drug manufacturer and also from other manufacturers, we should not penalize all manufacturers of the drug if one manufacturer fails to submit ASP data. The drug manufacturer further asked us to clarify whether the ASP conditional policy will apply to payments made on or after 2020 or to ASP data reported in 2020.

Response: First, we would like to reassure the commenters that the intent of our proposal was to apply this policy on an individual product basis. That is, under the revisions to § 413.234(c), we would condition the TDAPA for an individual renal dialysis drug or biological product on the availability of ASP data for that product. We would not condition the TDAPA for an individual drug or biological product on the availability of ASP data from all manufacturers of that drug or biological product. For example, if drug X is manufactured by manufacturer A and manufacturer B and manufacturer A does not make ASP data available to CMS but manufacturer B does, we would not apply the ASP conditional policy to manufacturer B's drug. That is, the ESRD facility would not receive the TDAPA when reporting on ESRD facility claims drug X from manufacturer A.

With regard to whether the ASP conditional policy will apply to payments made on or after January 1, 2020 or to ASP data reported in 2020, we note that this policy would become

effective January 1, 2020. Therefore, for a renal dialysis drug or biological product for which we are currently paying the TDAPA and for which ASP data is currently being reported, beginning January 1, 2020, if CMS does not receive the latest full calendar quarter of ASP data for the product, CMS will no longer apply the TDAPA beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

Comment: Several commenters were concerned that this policy could create consequences such as increased costs to ESRD facilities, which is particularly problematic for small and independent facilities, and could lead to facilities choosing not to furnish those drugs or biological products, which could decrease access for their patients. One commenter also argued this policy would complicate the collection of utilization data and thereby negatively affect how these drugs and biological products would be incorporated into the ESRD PPS bundled payment. Another commenter asserted that this proposal would impact the continuity of patient care and cause confusion in the billing and ordering process. A national dialysis stakeholder organization stated that it did not believe this policy would actually increase ASP reporting as it is intended to do.

Response: We understand the commenters' concerns. However, we continue to be concerned that drug manufacturers who are not otherwise required to submit ASP data to CMS would delay submission or withhold ASP data from CMS so that ESRD facilities would receive a higher basis of payment for the TDAPA and be incentivized to purchase drugs from those manufacturers. Additionally, we believe that this policy will incentive ASP reporting and ESRD facilities will want to provide the new renal dialysis drugs and biological products that are eligible for the TDAPA to their patients. We expect that, as the number of drugs and biological products within each ESRD PPS functional category increases and market share competition

from the manufacturers is a factor, there would be easier access, more choices in care and lower prices.

Comment: Several commenters recognized the issue of underreporting of ASP data that CMS was trying to solve, but preferred that CMS use other mechanisms to enforce ASP reporting. One commenter suggested CMS use Average Manufacturer Price (AMP) after a certain period of time of ASP not being reported. One drug manufacturer suggested that we allow a temporary deferment or exclusion from the ASP conditional policy when manufacturers encounter extraordinary circumstances beyond their control.

Response: We thank the commenters for their suggestions. We have the same concern with AMP as we do with WAC and invoice pricing in that it is more expensive than ASP. We continue to believe ASP data is the best data available for the purposes of the TDAPA since it is commonly used to facilitate Medicare payment across care settings and is based on the manufacturer's sales to all purchasers (with certain exceptions) and is net of manufacturer rebates, discounts, and price concessions. We also believe that our policy provides sufficient time to deal with extraordinary circumstances, so it is not necessary to establish that type of exception. However, we will monitor the effects of this proposal and consider these suggestions for future rulemaking.

Comment: One LDO suggested that CMS's motivation for proposing this policy was the perception that ESRD facilities were putting financial gain over the wellbeing of the patients. The LDO explained that when the new IV and generic oral calcimimetics became available the LDO followed the guiding principle that patients deserve access to the formulation that best meets their needs, while also remaining mindful of overall system costs.

Response: We appreciate that the commenter is focused on providing its patients with

access to formulations that best meet their clinical needs. However, we believe the comment about our motivation for this policy is unfounded. As noted previously, we based this proposal on our concerns about (1) increases to Medicare expenditures due to TDAPA for calcimimetics; (2) drug manufacturers not reporting ASP data for drugs eligible for TDAPA; and (3) our TDAPA policy potentially incentivizing drug manufacturers to withhold ASP data from CMS.

Comment: MedPAC and a non-profit provider association were supportive of conditioning the TDAPA on the availability of ASP data. Both suggested CMS consider going further by either requiring all Part B drug manufacturers to report ASP data, or by not applying the TDAPA to all eligible drugs from a noncompliant manufacturer rather than just the new renal dialysis drug or biological product for which the manufacturer is not reporting ASP data.

One national dialysis association supported MedPAC's suggestion that CMS take steps to ensure manufacturers report ASP data. However, the association specifically disagreed with MedPAC that CMS should require all Part B drug manufacturers report ASP data and believed any such requirement should be imposed directly on drug manufacturers under CMS authorities, and not on ESRD facilities.

Response: We have authority under section 1881(b)(14)(D)(iv) of the Act to include under the ESRD PPS such other payment adjustments as the Secretary determines appropriate, and we established the TDAPA for new renal dialysis drugs and biological products under this authority. We also have authority to place conditions on those payment adjustments, as we have otherwise done for the TDAPA by requiring that the renal dialysis drug or biological product meet certain eligibility criteria under § 413.234. At this time, we believe this policy appropriately targets the condition on the particular renal dialysis drug or biological product for which CMS has not received ASP data. We will take these suggestions under consideration for

future rulemaking.

Comment: A national dialysis association explained that its review of the publicly available data on Medicare's spending on calcimimetics indicate that Medicare spending has decreased under the TDAPA as compared to prior payment policies. The commenter stated that it cannot identify a data source that supports CMS' claim of a $1.2 billion increase in Medicare spending on calcimimetics in CY 2018. On the contrary, the commenter's review of the data indicates that Medicare spending on calcimimetics decreased under the TDAPA from more than $1.4 billion in CY 2017 to $1 billion represented in the file containing 85 percent of the claims in CY 2018. The commenter believes that because calcimimetics moved from Part D spending to Part B spending in CY 2018, that CMS should not claim an increase in Part B spending. The commenter stated that if there is another source of data that the public should review in order to fully evaluate CMS' claims, then that data should be made available along with the rulemaking. The commenter further asserted that as CMS's statement of an increase in Medicare spending on calcimimetics is not correct or corroborated by the data, it is not adequate justification for the proposal to condition the TDAPA on the provision of ASP data.

An LDO noted the decrease in expenditures due to calcimimetics discussed in the comment from the national dialysis association and stated that the data was inconsistent with CMS' analysis in the proposed rule.

Response: In response to the commenter's questions about the $1.2 billion increase in Medicare costs for calcimimetics, we clarify that the $1.2 billion figure refers to expenditures under the ESRD PPS for CY 2018, as reflected in claims, due to the utilization of calcimimetics alone. We do not believe that it is appropriate to consider expenditures in other Medicare or Medicaid funding areas when developing policies under the ESRD PPS. These funding areas are

not co-mingled or mutually interchangeable. In addition, the Part B spending includes the injectable form of the calcimimetic which was not covered under Part D. We have further reviewed our data for CY 2018 and stand by the stated 1.2 billion increase to ESRD PPS expenditures.

Final Rule Action: After consideration of public comments, we are finalizing the ASP conditional policy as proposed, effective January 1, 2020. Under our final policy, the basis of payment for the TDAPA for all new renal dialysis drugs and biological products is ASP+0, but if ASP is not available then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice. We are revising § 413.234(c) to state that notwithstanding the provisions in paragraphs (c)(1) and (2) of that section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for the product, CMS will no longer apply the TDAPA for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. In addition, if CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of § 413.234, CMS will no longer apply the TDAPA for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

3. New and Innovative Renal Dialysis Equipment and Supplies under the ESRD PPS

a. Background on Renal Dialysis Equipment and Supplies under the ESRD PPS

In the CY 2011 ESRD PPS final rule (75 FR 49075), we stated that when we computed the ESRD PPS base rate, we used the composite rate payments made under Part B in 2007 for

dialysis in computing the ESRD PPS base rate. These are identified in Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as "Composite Rate Services". Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. As we indicated in the CY 2011 ESRD PPS proposed rule (74 FR 49928), the case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). In the CY 2011 ESRD PPS final rule (75 FR 49062), we noted that total composite rate costs in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs.

Currently, ESRD facilities are required to report their use of syringes on claims in order to receive separate payment, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49141). However, historically, ESRD facilities were not required to report any other renal dialysis equipment and supplies on claims (with the exception of syringes) because these items were paid through the composite rate and did not receive separate payment. As discussed in the Medicare Claims Processing Manual (chapter 8, section 50.3), CMS directs ESRD facilities to report a dialysis treatment and their charge for the treatment. That charge is intended to reflect the cost of the dialysis treatment (equipment, supplies, and staff time) as well as routine drugs and laboratory tests. This manual is available on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf.

In the CY 2019 ESRD PPS final rule (83 FR 56942 through 56943), we finalized an expansion of the TDAPA to all new renal dialysis drugs and biological products. As part of the

CY 2019 ESRD PPS rulemaking, we received several comments regarding payment under the ESRD PPS for certain new, innovative equipment and supplies used in the treatment of ESRD. For example, as we described in the CY 2019 ESRD PPS final rule (83 FR 56972), a device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new devices that have been granted marketing authorization by FDA. They commented on the lack of new devices granted marketing authorization by FDA for use in an ESRD facility, highlighting the need to promote dialysis device innovation. The commenters indicated they believed the same rationale CMS used to propose broadening the TDAPA eligibility also would apply to new devices. Specifically, the commenters noted that CMS has discretionary authority under section 1881(b)(14)(D)(iv) of the Act to adopt payment adjustments determined appropriate by the Secretary, and stated that precedent supports CMS' authority to use non-budget neutral additions to the ESRD PPS base rate for adjustments under specific circumstances.

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 (83 FR 56973). The association stated that additional money should be made available to appropriately reflect the costs of new devices under the ESRD PPS bundled payment. A national dialysis organization and a large dialysis organization (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. The organization stated that 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 ESRD PPS bundled

payment.

In addition, as we discussed in the CY 2019 ESRD PPS final rule (83 FR 56973), an LDO requested CMS plan appropriately for innovative devices or other new and innovative products and asked CMS to work with the kidney care community to consider if and how new devices or other new and innovative products delivering high clinical value, can be made available 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 for adding new devices to the ESRD PPS bundled payment, stating that it left investors and industry wary of investing in the development of new devices for patients. In response to these comments, we expressed appreciation for the commenters' thoughts regarding payment for new and innovative devices, and stated that we did not include any proposals regarding this issue in the CY 2019 ESRD PPS proposed rule, so we considered these suggestions to be beyond the scope of that rule.

Also, 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 and 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, we noted, 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 received mixed feedback in response to the comment solicitation, which was summarized in the CY 2019 ESRD PPS final rule (83 FR 56969 through 56970). Some LDOs and national dialysis organizations stated that they would prefer a smaller outlier pool with more money in the per treatment base rate while other ESRD facilities agreed that the outlier policy should be more comprehensive and expanded to include more items and services. In our response, we stated we recognized 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 indicated we would take these views into account as we consider the outlier policy and payment adjustments for future rulemaking.

In light of these comments, in the CY 2020 ESRD PPS proposed rule (84 FR 38350 through 38357), we considered whether additional payment may be warranted for certain new and innovative renal dialysis equipment and supplies. In the CY 2020 ESRD PPS proposed rule, we provided a general description of the IPPS new technology add-on payment (NTAP) and its SCI criteria, and we include that description again in sections II.B.3.a.i and II.B.3.a.ii of this final rule. We stated that we believe a process similar to the IPPS process for establishing SCI for the NTAP could be used to identify the innovative renal dialysis equipment and supplies for which commenters were requesting additional payment under the ESRD PPS. We noted that we believed an NTAP-like payment adjustment under the ESRD PPS would be appropriate in order to support innovation while being responsive to stakeholders.

i. Add-On Payments for New Technology under the Inpatient Prospective Payment System

In the CMS Innovators' Guide to Navigating Medicare[28], we explain that the hospital IPPS makes payments to acute care hospitals for each Medicare patient or case treated. Hospitals are paid based on the average national resource use for treating patients in similar circumstances, not the specific cost of treating each individual patient. With few exceptions, Medicare does not pay separately for individual items or services. Physicians and hospital staff determine the appropriate course of treatment, and hospitals receive a bundled payment for the covered inpatient facility services provided to the Medicare patient. Hospitals receive one IPPS payment per Medicare case at discharge that equates to the total Medicare payment for the facility costs of caring for that Medicare patient. More information on determining IPPS payment is located on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html

Also as discussed in the CMS Innovators' Guide to Navigating Medicare[29], the IPPS is designed to adapt to changing technology through year-to-year adjustments in Medicare Severity – Diagnosis Related Groups (MS-DRG) weights based on historical cost data. In theory, if new technologies lead to better care but are more expensive, or if they lead to more efficient care and are less expensive, hospitals will eventually receive appropriate payment as the MS-DRG weights are adjusted over time to reflect the impact of fluctuating costs. In practice, however, there are concerns that the system may be slow to react to rapidly evolving technological advancements.

Hospitals may experience a financial disadvantage as they provide more expensive products and services to Medicare beneficiaries while waiting for MS-DRG payments to reflect

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28 https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf
29 https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf

the higher costs. Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. As an incentive for hospitals to adopt new technologies during the period before their costs are recognized in the MS-DRG weights, certain new medical services or technologies may be eligible for new technology add-on payments. The new technology add-on payment policy provides additional payments for eligible high cost cases without significantly eroding the incentives provided by a payment system based on averages. To qualify for add-on payments, the regulations at 42 CFR 412.87 generally specify a medical service or technology must be: (1) new, (2) demonstrate a SCI over existing technology, and (3) be high cost such that the MS-DRG payment that would normally be paid is inadequate. For a complete discussion on the new technology add-on payment criteria, we refer readers to the fiscal year (FY) 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Since it can take 2 to 3 years for reflection of cost data in the calculation of the MS-DRG weights, technologies generally are considered new for 2 to 3 years after they become available. Applicants must demonstrate that their product offers SCI and the other NTAP requirements.

Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed the threshold amount for the MS-DRG (or the case-weighted average of all relevant MS-DRGs, if the new technology could be assigned to many different MS-DRGs).

Although any interested party may submit an application for a new technology add-on payment, applications often come from the manufacturer of a new drug or device. Preliminary

discussions on whether or not new technologies qualify for add-on payments are published in the annual IPPS proposed rules and are open to public comment.

The actual add-on payments are based on the cost to hospitals for the new technology. A new technology add-on payment is made if the total covered costs of the patient discharge exceed the MS-DRG payment of the case (including adjustments for indirect medical education (IME) and disproportionate share hospital (DSH), but excluding outlier payments). The total covered costs are calculated by applying the cost-to-charge ratio (that is used for inpatient outlier purposes) to the total covered charges of the discharge.

Under § 412.88, if the costs of the discharge exceed the full MS-DRG payment, the additional payment amount equals the lesser of the following: (1) 50 percent of the costs of the new medical service or technology; (2) or 50 percent of the amount by which the total covered costs of the case (as determined above) exceed the standard MS-DRG payment, plus any applicable outlier payments if the costs of the case exceed the MS-DRG, plus adjustments for IME and DSH. More information on IPPS new technology add-on payments, including the deadline to submit an application, is located on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.

ii. SCI Criteria for the New Technology Add-On Payment under the IPPS

Under section 1886(d)(5)(K)(vi) of the Act, a medical service or technology will be considered a “new medical service or technology” if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment. For a more complete discussion of the establishment of the current criteria for the new technology add-on payment, we refer readers to the IPPS final rule published on September 7, 2001 in the **Federal**

Register (66 FR 46913), referred to as "FY 2001 IPPS final rule," where we finalized the "substantial improvement" criterion to limit new technology add-on payments under the IPPS to those technologies that afford clear improvements over the use of previously available technologies. Specifically, we stated that we would evaluate a request for new technology add-on payments against the following criteria to determine if the new medical service or technology would represent a SCI over existing technologies:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. We also noted examples of outcomes that are frequently evaluated in studies of devices. For example,

++ Reduced mortality rate with use of the technology.

++ Reduced rate of technology related complications.

++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

++ Decreased number of future hospitalizations or physician visits. More rapid beneficial resolution of the disease process treatment because of the use of the device.

++ Decreased pain, bleeding, or other quantifiable symptom.

++ Reduced recovery time.

In the FY 2001 IPPS final rule (66 FR 46913), we stated that we believed the special payments for new technology should be limited to those new technologies that have been demonstrated to represent a substantial improvement in caring for Medicare beneficiaries, such that there is a clear advantage to creating a payment incentive for physicians and hospitals to utilize the new technology. We also stated that where such an improvement is not demonstrated, we continue to believe the incentives of the DRG system would provide a useful balance to the introduction of new technologies. In that regard, we also pointed out that various new technologies introduced over the years have been demonstrated to have been less effective than initially thought, or in some cases even potentially harmful. We stated that we believe that it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.

We noted in the FY 2020 IPPS proposed rule (84 FR 19274 through 19275), that applicants for add-on payments for new medical services or technologies must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a SCI, along with a significant sample of cost data to demonstrate that the medical service or technology meets the cost criterion. Complete application information, along with final deadlines for submitting a full application, is posted on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.

Per section 1886(d)(5)(K)(i) of the Act, the Secretary is required to establish a mechanism to recognize the costs of new medical services and technologies under the payment

system after notice and opportunity for public comment. The payment rate updates and policy changes including new technology add-on payments under the IPPS are completed through the annual notice-and-comment rulemaking process with an October 1 effective date. In the proposed rule, CMS reviews each application and the information and clinical evidence provided by the applicant on how it meets each of the new technology add-on payment criteria. Regarding SCI, we work with our medical officers to evaluate whether a technology represents an SCI. Under the IPPS, public input before publication of a notice of proposed rulemaking on add-on payments is required by section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108–173, and provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a SCI or advancement. In the final rule, we make a determination whether an applicant has met the new technology add-on payment criteria and is eligible for the add-on payment.

The IPPS proposed and final rules go on display around April and August, respectively, each year. The FY 2020 IPPS proposed rule is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices-Items/CMS-1716.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

b. Proposed Transitional Add-on Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

As we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38350 through 38353), following publication of the CY 2019 ESRD PPS final rule (83 FR 56969 through 56970), which discussed the comment solicitation on expanding the outlier policy to include composite rate drugs and supplies, we received additional information from dialysis equipment and supply

manufacturers and a TEP meeting held in December 2018 regarding composite rate equipment and supplies. Discussions of the key findings from the TEP meeting can be found in section VIII.A of this final rule. In addition, some manufacturers have informed us that there is little incentive for them to develop innovative equipment and supplies for the treatment of ESRD primarily because ESRD facilities have no incentive to adopt innovative dialysis equipment and supplies since they are included in the ESRD PPS bundled payment and currently no additional payment is made.

In addition, we stated that we believed innovations in kidney care are likely as a result of the Kidney Innovation Accelerator (known as KidneyX). KidneyX is a public-private partnership between the Department of Health and Human Services and the American Society of Nephrology to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.

KidneyX seeks to improve the lives of dialysis patients by accelerating the development of drugs, devices, biologics and other therapies across the spectrum of kidney care including prevention, diagnostics, and treatment. KidneyX's first round of prize funding focused on accelerating the commercialization of next-generation dialysis products, aiming to reduce the risk of innovation by streamlining processes, reducing regulatory barriers, and modernizing the way we pay for treatment. More than 150 applications were reviewed, covering a full-range of innovative proposals, including advances in access, home hemodialysis and peritoneal dialysis, adjuncts to current in-center dialysis, and proposals for implantable devices, externally-worn devices and prototypes for an artificial kidney. More information regarding KidneyX is available at the following link: http://www.kidneyx.org/.

We stated that we believed some of the prototypes developed as part of the KidneyX will

be the type of innovation the commenters requested and we want to incentivize ESRD facility use of those products. We noted that in order for equipment and supplies awarded through the KidneyX to be eligible for the additional payment the items would also need to be determined by CMS to be a renal dialysis service and meet other eligibility criteria described in section II.B.3.b.i of the CY 2020 ESRD PPS proposed rule (84 FR 38353 through 38355). We also noted that the goals for KidneyX and our proposal are different but complementary; KidneyX is focused on accelerating innovation in the prevention, diagnosis, and treatment of kidney disease, at the beginning stages of the development of an innovative product, while our proposals were intended to support uptake of new and innovative renal dialysis equipment and supplies after they have been authorized for marketing by FDA and meet other requirements, all of which happen after the development stage.

In addition, on July 10, 2019, the President signed an Executive Order[30] aimed at transforming kidney care in America. The Executive Order established many initiatives, including the launch of a public awareness campaign to prevent patients from going into kidney failure and proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease and encouraging the development of breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available.

i. Proposed Eligibility Criteria for Transitional Add-on Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies

As we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354 through 38355), in consideration of the feedback we have received, we agree that additional payment for certain

30 https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/

renal dialysis equipment and supplies may be warranted under specific circumstances. We proposed to provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities (with the exception of capital-related assets). We proposed to call this payment adjustment the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies or TPNIES.

Renal dialysis equipment and supplies are medically necessary equipment and supplies used to furnish renal dialysis services in a facility or in a patient's home. We proposed that "new" renal dialysis equipment and supplies are those that are granted marketing authorization by FDA on or after January 1, 2020. By including FDA marketing authorizations on or after January 1, 2020, we intend to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. We solicited comment on this aspect of our proposal and whether a different FDA marketing authorization date—for example, on or after January 1, 2019—might be appropriate.

We stated in the CY 2020 ESRD PPS proposed rule that, for new and innovative equipment and supplies, we believed the IPPS SCI criteria and the process used to evaluate SCI under the IPPS can be used as a proxy for identifying new and innovative equipment and supplies worthy of additional payment under the ESRD PPS. We noted that under the IPPS, CMS has been assessing new technologies for many years to assure that the additional new technology add-on payments to hospitals are made only for truly innovative and transformative products, and we stated that CMS is proposing to adopt the IPPS SCI criteria under the ESRD PPS for the same reason. We explained that we wanted to ensure that the add-on payment adjustments made under the ESRD PPS are limited to new equipment and supplies that are truly innovative. In addition, since renal dialysis services are routinely furnished to hospital inpatients

and outpatients, we stated that we believed the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under Medicare.

Therefore, we proposed to adopt IPPS's SCI criteria specified in § 412.87(b)(1), including modifications finalized in future IPPS final rules, to determine when a new and innovative renal dialysis equipment or supply is eligible for the TPNIES under the ESRD PPS. That is, we would adopt IPPS's SCI criteria in § 412.87(b)(1) and any supporting policy around this criteria as discussed in IPPS preamble language. We stated that we believed that by incorporating the IPPS SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have standard criteria to meet for both settings. We also proposed to establish a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87(b)(1). That is, we proposed that CMS would use a similar process to determine whether the renal dialysis equipment or supply meets the eligibility criteria proposed in newly added § 413.236(b). Similar to how we evaluate whether a new renal dialysis drug or biological product is eligible for the TDAPA, as discussed in the CY 2016 ESRD PPS final rule (80 FR 69019), we would need to determine whether the renal dialysis equipment and supply meets our eligibility criteria for the TPNIES.

We noted that IPPS has additional criteria that is specific to its payment system, that is, a high cost criteria relative to the MS-DRG payment. We did not propose to adopt the specific IPPS high cost criteria requirements under § 412.87(b)(3) under the ESRD PPS since the basis of payment is different. Specifically, under the ESRD PPS, the basis of payment is the per treatment payment amount that is updated annually by the ESRD bundled market basket and the multifactor productivity (MFP) adjustment. For this reason we only proposed to adopt the SCI

criteria in § 412.87(b)(1) and did not consider the high cost criteria requirements.

We proposed to exclude capital-related assets from eligibility for the TPNIES, which we would define based on the Provider Reimbursement Manual (Pub. L. 15-1) (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). The Provider Reimbursement Manual is available on the CMS website at https://www.cms.gov/NoRegulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html. We explained that this would include certain renal dialysis equipment and supplies. An examples of a capital-related asset for ESRD facilities could include water purification systems. We stated that we did not believe that we should provide an add-on payment adjustment for capital-related assets because the cost of these items are captured in cost reports, depreciate over time, and are generally used for multiple patients. Since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. We therefore stated that we believed capital-related assets should be excluded from the TPNIES at this time, and proposed an exclusion to the eligibility criteria in new § 413.236(b)(2). However, we noted that capital-related asset cost data from cost reports are used by CMS in regression analyses to refine the ESRD PPS so that the cost of any new capital-related assets is accounted for in the ESRD PPS payment adjustments.

Under our proposal, in addition to having marketing authorization by FDA on or after January 1, 2020, and meeting SCI criteria as determined under § 412.87(b)(1), the equipment or supply must be commercially available, have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and have been designated by CMS as a renal dialysis service under § 413.171. We proposed that following FDA marketing authorization, in order to establish a mechanism for payment, the equipment or supply would then go through a

process to establish a billing code, specifically a HCPCS code. This information is necessary to conform to the requirements for both CMS and provider billing systems. Information regarding the HCPCS process is available on the CMS website at https://www.cms.gov/medicare/coding/MedHCPCSGenInfo/Index.html.

Under our proposal, we would model our determination process similar to that of IPPS's NTAP. That is, manufacturers would submit all information necessary for determining that the renal dialysis equipment or supply meets the eligibility criteria listed in § 413.236(b). That would include FDA marketing authorization information, the HCPCS application information, and studies submitted as part of these two standardized processes, an approximate date of commercial availability, and any information necessary for SCI criteria evaluation. For example, clinical trials, peer reviewed journal articles, study results, meta-analyses, systematic literature reviews, and any other appropriate information sources can be considered.

We proposed to provide a description of the equipment or supply and pertinent facts related to it that can be evaluated through notice-and-comment rulemaking. We stated that we would consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in newly added § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In order to implement the TPNIES for a particular calendar year, we would only consider a complete application received by CMS by February 1 prior to the particular calendar year.

For example, under our proposal, in order to receive the TPNIES under the ESRD PPS effective January 1, 2022 we would require that a complete application meeting our requirements be received by CMS no later than February 1, 2021. Then, we would include a discussion of the renal dialysis equipment or supply requesting the TPNIES in the CY 2022 ESRD PPS proposed

rule. Our evaluation of the eligibility criteria would be addressed in the CY 2022 ESRD PPS final rule. If the renal dialysis equipment or supply qualifies for the TPNIES, payment would begin January 1, 2022.

Alternatively, we considered an application deadline of September 1, however, we proposed an earlier timeframe so that the TPNIES would be implemented sooner. We noted that a September 1 deadline would provide more time initially for manufacturers to submit applications. We solicited comment on the proposed deadline date for the application.

To codify the requirements for the TPNIES, including the eligibility, we proposed to add § 413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies. We proposed to add § 413.236(a) to state that the basis for the section is to establish a payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD PPS under the authority of section 1881(b)(14)(D)(iv) of the Act.

We proposed to add § 413.236(b) to address the eligibility requirements for the TPNIES. Under the proposed paragraph (b), for dates of service occurring on or after January 1, 2020, we would provide a TPNIES as specified in paragraph (d) that is added to the per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics as described in §§ 413.232 and 413.235 to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available, (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures, (5) is innovative, meaning it meets the

criteria specified in § 412.87(b)(1) and related guidance, and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

We also proposed to add § 413.236(c) to establish a process for the TPNIES eligibility determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. That is, we proposed that we would consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. We proposed that we would only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the TPNIES would take effect.

We solicited comment on the proposed criteria to determine new and innovative renal dialysis equipment and supplies that would be eligible for TPNIES. In addition, we solicited comment on the use of different evaluative criteria and, where applicable, payment methodologies, for renal dialysis supplies and equipment that may be eligible for the TPNIES under the ESRD PPS. These criteria could include cost thresholds for high cost items. We solicited comment on whether any of the IPPS SCI criteria would not be appropriate for the ESRD facility setting and whether there should be additional criteria specific to ESRD. We sought comment on whether to use FDA's pre-market authorization and De Novo pathways as a proxy for or in place of the proposed SCI criteria. In addition, we solicited comment on potential implementation challenges, such as what sources of data that CMS should utilize to assess SCI and the proposed process that would be used to determine SCI. Finally, we solicited comment on the benefits and drawbacks of the proposed SCI criteria.

The comments and our responses to the comments on our proposals regarding eligibility criteria for the TPNIES are set forth below.

Comment: All of the comments we received supported the establishment of the TPNIES to spur innovation for new renal dialysis equipment and supplies. Several commenters expressed support for the proposed TPNIES definition of "new" and "innovative" as a device granted FDA marketing authorization that demonstrates SCI using criteria similar to those applied under the IPPS NTAP. MedPAC and an LDO also expressed support for the process outlined in the CY 2020 ESRD PPS proposed rule. MedPAC expressed support for transparent and predictable processes with established routines for the agency, stakeholders, and the public. MedPAC pointed out that the proposed annual process of review for TPNIES eligibility provides manufacturers a forum for feedback and questions, and it provides other stakeholders with opportunities to participate in the process.

Response: We appreciate the commenters' support.

Comment: A physician association stated that it is critical to support innovation in kidney care, but stressed that there must also be a specific focus on innovations that also pertain to the pediatric space. New products and therapies that come to market are not always tested in the pediatric population or are even appropriate for children, and. policies must be put in place to change this moving forward. The association emphasized that children and adolescents are not simply "little adults." Rather, they have a unique physiology characterized by maturing organ function, body metabolism, and body distribution characteristics distinct from what adults manifest. Due to these differences, the safety and efficacy data of equipment and supplies developed for adults and only studied in adults may not be appropriate for pediatric patients. The association acknowledged that the small number of pediatric patients complicates

conducting safety, efficacy, or interventional trials in children, but stated that the importance of this data is crucial to allow children to also benefit from innovation.

Response: We hope that by providing the TPNIES, equipment and supply manufacturers will develop new and innovative renal dialysis products for pediatric patients as well as adult patients and that the clinical trials conducted for such products include pediatric patients. By establishing the TPNIES for new and innovative renal dialysis equipment and supplies, we believe that manufacturers will be encouraged to develop new products, including new and innovative products for pediatric patients. We note that our data analysis contractor will be holding a TEP meeting in December 2019 and intends to address the topic of pediatric dialysis.

Comment: Most stakeholders expressed concern that the TPNIES proposal excludes capital-related assets. A national dialysis stakeholder organization and an LDO requested that CMS propose in the next rulemaking a pathway for accounting for new capital equipment in the ESRD PPS. The organization pointed out that the IPPS NTAP payment for new devices does not address capital equipment because those costs are incorporated in the base rates using other mechanisms linked to the cost reports. As there is no similar mechanism under the ESRD PPS, the organization asked that CMS propose in the CY 2021 ESRD PPS proposed rule a mechanism that would adjust the ESRD PPS base rate to account for the cost of innovative renal dialysis capital equipment as well. The organization stated that this policy is important because many innovative devices, including some that the President has highlighted, would be capital equipment. A device manufacturer also recommended that we propose to include purchased capital equipment in the CY 2021 ESRD PPS proposed rule.

An LDO stated that the proposed eligibility for the TPNIES is overly narrow, and does not address the need and potential for achieving innovations in the most central component of

dialysis care. A professional association agreed, noting that significant innovation and technology improvement is occurring in the area of dialysis machines and peritoneal dialysis cyclers and that innovation in the efficiency and effectiveness of water systems would both improve patient quality of care, as well as reduce costs for facilities and help to preserve the nation's water supply.

Another LDO also recommended that CMS eliminate the exclusion for capital-related assets from the TPNIES criteria. The LDO noted it is sensitive to the operational challenges highlighted by CMS that would emerge if capital-related assets were eligible for the TPNIES. The LDO expressed appreciation for CMS' desire to arrive at a policy that is operationally simple but maintained that the challenges cited by CMS in applying the TPNIES to capital-related assets can be overcome. Alternatively, the LDO recommended that CMS consider a separate add-on payment methodology to capture the costs of capital-related assets under its existing authority to include other payment adjustments in the ESRD PPS as the Secretary determines appropriate.

MedPAC stated that the proposal is unclear about whether capital-related assets that are leased are excluded from eligibility for the TPNIES. MedPAC pointed out that in the proposed rule, the definition of a capital-related asset refers to the Provider Reimbursement Manual (Chapter 1, Section 104.1), which does not distinguish between capital-related items that are purchased versus those that are leased. MedPAC requested that we clarify in the CY 2020 ESRD PPS final rule whether a capital-related asset that is leased would be eligible for the TPNIES.

A health services company recommended that CMS clarify that equipment or supplies used for home dialysis are not subject to the "capital-related asset" criteria and confirm that a

leased home dialysis device would not be a capital-related asset. The company stated that our proposal uses the hospital cost reporting definition of a depreciable asset, which it strongly believes should not apply in the case of home dialysis equipment or supplies that are not used by multiple patients in a facility but rather are used exclusively by a single patient in the patient's home. The company indicated that this change to the eligibility criteria would help better align the TPNIES with the Administration's bold goals for moving kidney care away from its current reliance on in-center dialysis to more availability and use of home dialysis. A device manufacturer stated that including leased capital equipment is feasible under the currently proposed payment approach, leveraging existing coding mechanisms and the proposed invoice-based payment process.

An LDO acknowledged that the cost report design may make it difficult to differentiate capital-related assets on a per treatment basis and that is why CMS proposed to exclude capital-related assets. However, the LDO stated that in doing so, in effect, CMS is only creating a payment adjustment for renal dialysis supplies. Until the work can be accomplished to differentiate capital related assets on cost reports, the commenter suggested that CMS only exclude capital-related assets generally used for multiple patients. The commenter stated that by allowing single patient use equipment, CMS would be fostering more patient-engaged solutions like those found in the Kidney X prize competition and for home modalities.

A patient advocacy organization stated that while it appreciates the complexity involved in establishing a payment adjustment for capital-related assets on a per-treatment basis, the organization believes it is critically important to implement incentives that may result in lighter and easier to use home dialysis machines, especially given the Administration's efforts to increase the uptake of home dialysis. The organization stated that home dialysis machines are

both leased and purchased by facilities, so it believes both types of machines should ultimately be eligible for the TPNIES, though it supports CMS' efforts to begin with considering leased equipment for eligibility.

Response: As we stated in the CY 2020 ESRD PPS proposed rule, we do not believe that we should provide the TPNIES for capital-related assets because the cost of these items is captured in cost reports, depreciate over time, and are generally used for multiple patients. Additionally, since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. Therefore, we proposed to exclude capital-related assets from eligibility for the TPNIES in new § 413.236(b)(6). Further, we believe providing the TPNIES for capital-related assets is complex given the various leasing arrangements and depreciation.

While we acknowledge that significant innovation and technology improvement is occurring with dialysis machines and peritoneal dialysis cyclers, as well as innovation in the efficiency and effectiveness of water systems, at this time we do not have enough information regarding current usage of the various financial and leasing arrangements, such as those involving capital-leases for depreciable assets versus operating leases recorded as operating expenses. In addition, methodological issues regarding depreciation need to be assessed in order to determine whether TPNIES eligibility for these items would be appropriate. We need to further study the specifics of the various business arrangements for equipment related to renal dialysis services. This would include items that are: (1) purchased in their entirety and owned as capital-related assets; (2) assets that are acquired through a capital- lease arrangement; (3) equipment obtained through a finance lease and recorded as an asset per the Financial Accounting Standards Board (FASB) guidance on leases (Topic 842) effective for fiscal years

beginning after December 15, 2018,[31] or (4) equipment obtained through an operating lease and recorded as an operating expense. In addition to the variety of business arrangements, there are unknown issues relating to ownership of the item and who retains title, which flows into the equipment's maintenance expenses for capital-related assets. Further, there is the question of the definition of single use versus multiple use for equipment used for renal dialysis services. For example, capital-related assets used in-center and in the home may be used by multiple patients over their useful lifetime. Specifically, equipment classified as capital-related assets may be refurbished and used by another patient. At this time, we are unable to adequately assess the eligibility of these items for the TPNIES. We intend to gather additional information about how ESRD facilities obtain their capital-related equipment in future meetings with the TEP.

With regard to capital-lease equipment for home dialysis, we note that historically we have always supported patient choice with regard to dialysis modality and we support the Administration's initiatives for home dialysis. However, we did not intend for capital-lease assets to be eligible for the TPNIES at this time. We note that regulations at § 413.130(b)(1) "Introduction to capital-related costs," specifies that leases and rentals are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. In the future, we will be closely examining the treatment of capital-related assets under Medicare, including our regulations at § 412.302 regarding capital costs in inpatient hospitals and § 413.130, as they relate to accounting for capital-related assets, including capital-lease and the newly implemented guidance for finance lease arrangements, to determine if similar policies would be appropriate under the ESRD PPS.

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31 FASB Accounting Standards Update: No. 2016-02, February 2016; Leases (Topic 842); An Amendment of the FASB Accounting Standards Codification. https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=1176167901010&acceptedDisclaimer=true.

Comment: A device manufacturers' association pointed out that since most medical equipment is purchased as a capital-related asset, the TPNIES effectively would exclude the innovative equipment identified in the title of the adjustment. The association noted that meaningful clinical improvements and patient experience improvements are arguably more likely to come from innovation outside single-use supplies. The association stated that expanding the TPNIES to include medical equipment, regardless of how it is purchased by the provider, would stimulate greater investment in a broader array of new technologies for ESRD patients.

Response: We recognize that accounting for renal dialysis service equipment can vary depending on the individual ESRD facility's business model. For example, when the owner of the capital-related asset retains title, then the renal dialysis service equipment is a depreciable asset and depreciation expense could be itemized. When there is no ownership of the renal dialysis service equipment, then the item is recorded as an operating expense. We disagree with the commenter and believe that there could be new and innovative equipment that are not capital-related assets and could therefore be eligible for the TPNIES. For example, there could be a supply or piece of equipment that is purchased outright by the ESRD facility that may be able to withstand repeated use over the treatment month and lasts less than a year, that does not fall under the definition of capital-related asset in § 413.236(b)(6).

Comment: A device manufacturer recommended that CMS change the definition of the TPNIES from new and innovative equipment and supplies to new and innovative equipment, supplies, and services. The manufacturer stated that this modification would align the ESRD PPS TPNIES definition with the IPPS NTAP and would clarify that the TPNIES would apply not only to new technologies, but also to new services that meet the SCI requirements. In addition to aligning the TPNIES definition with that of the IPPS NTAP, the manufacturer noted, this

modification would clarify that non-technology services that benefit ESRD patients can also qualify for the TPNIES if they meet the SCI criteria. The manufacturer stated that this is important because innovations to address care of ESRD patients are not limited solely to new technology. For example, novel home dialysis educational programs or remote monitoring services could create real benefit for ESRD beneficiaries, but would not necessarily be defined as technologies.

Response: Our proposal was limited to renal dialysis supplies and equipment that receive FDA marketing authorization, so we are unable to adopt this recommendation to include services in the definition of TPNIES for CY 2020.

Comment: A national dialysis stakeholder organization, a national dialysis association, an LDO and other commenters asked that CMS shift the application deadline for the TPNIES to later in the year. They expressed concern that the February 1 deadline may be difficult to meet, but the September deadline might not provide enough time for CMS to apply the TPNIES in the next calendar year.

Many commenters recommended that CMS adopt timelines that provide maximum flexibility to manufacturers in meeting the application deadline, particularly in the first year of the program and asked that CMS extend the February 1, 2020 application deadline to April or May. They stated that manufacturers would benefit from additional time in the first year of the program because the process will be new and manufacturers were not able to prepare for it during development of their products. More importantly, several commenters urged CMS to allow manufacturers to file applications for products that are expected to receive FDA authorization for marketing before the next calendar year, but not require that marketing authorization take place prior to the application deadline. The commenter pointed out that this

approach is allowed for the NTAP application, which requires only that a product is pending marketing authorization at the FDA at the time of filing the NTAP application.

Response: The commenters are correct that finalizing a September 1 deadline for submission of an application for the TPNIES would delay payment of the TPNIES for an entire year. In order to obtain public comment on the TPNIES application through the ESRD PPS rulemaking process, we would need to receive a complete application with sufficient information to include in the annual ESRD PPS proposed rule by February 1. We agree that a February 1 deadline, particularly for CY 2020, may not provide sufficient time for manufacturers with products in FDA review to meet the new requirements of § 413.236(c). However, our goal is to support uptake of new and innovative equipment and supplies for those manufacturers that are ready to supply ESRD facilities with these innovative products. Therefore, for CY 2020 we are finalizing the February 1 application deadline because we want to provide the opportunity for expedited payment of the TPNIES. We note that otherwise ESRD facilities would not receive the TPNIES for any equipment and supplies in CY 2021. We are clarifying that submissions to FDA for marketing authorization must have been submitted to FDA by the time the TPNIES application is submitted to CMS, that is, February 1. The FDA marketing authorization need not occur until September 1 of the same year so that we are able to finalize the TPNIES in the annual ESRD PPS final rule. We are revising § 413.236(c) to clarify that FDA marketing authorization must occur by September 1 in order for the product to be eligible for the TPNIES on January 1 of the following year. More information regarding TPNIES application submissions in CY 2020 is discussed later in this section.

Comment: As explained previously, we proposed to define new renal dialysis equipment and supplies as those that are granted marketing authorization by FDA on or after January 1,

2020. However, we solicited comment on whether a different FDA marketing authorization date, for example, on or after January 1, 2019, might be appropriate. Many commenters, including a device manufacturers association, a device manufacturer, a medical technology company, a national dialysis stakeholder organization, a national dialysis association, an LDO, and a home dialysis association expressed support for a January 1, 2019 FDA marketing authorization date.

One of the commenters suggested that CMS eliminate the newness criterion. The commenter stated that while little innovation has occurred in ESRD in decades, there are a limited number of products developed that have been unsuccessful in entering the market because of reimbursement barriers. The commenter asserted that the proposed January 1, 2020 date would encourage use of technologies that are currently in development, but have not yet entered the market, putting earlier innovators at a disadvantage. The commenter maintained that the same incentive for use should be applied to technologies that have recently gained approval and have had limited market uptake, in many cases because they are more costly than existing technologies, despite presenting substantial clinical improvement.

A software development company stated that it is important that CMS implement the TPNIES in a manner that maintains a level playing field. In other words, CMS must work collaboratively with FDA to ensure all new market entrants undergo the appropriate regulatory oversight prior to marketing their equipment and supplies. The company stated that CMS must also implement the TPNIES in a manner that avoids rewarding technology vendors for achieving overdue FDA marketing authorization. Further, technologies that have already completed the regulatory oversight process should be able to access the same incentives, that is, the new add-on payment adjustment.

The company encouraged CMS to ensure the eligibility of technologies that have already obtained FDA marketing authorization, and are not reimbursed under the ESRD PPS, for the TPNIES. This approach would assist CMS in achieving greater competition and innovation, as opposed to making eligible just those products granted marketing authorization by the FDA on or after January 1, 2020, as envisioned by the proposed rule.

Another commenter expressed similar concerns and recommended that CMS extend eligibility for the TPNIES to products receiving marketing authorization on or after January 1, 2019, and even consider on or after January 1, 2018 as the criterion. The commenter stated that this would allow a technology to be eligible for the TPNIES if it recently received marketing authorization but has struggled with market adoption because of financial disincentives in the ESRD PPS.

Another commenter recommended that CMS extend the eligibility for the TPNIES back to a January 1, 2018 FDA marketing authorization date. This would give new devices (and drugs) that may be eligible to participate in IPPS' NTAP or OPPS' pass-through, a 2-year window from the regulatory date of approval, or when the product is introduced to market, to participate in the respective programs. The commenter also noted that there have been highly innovative products, which could significantly benefit the Medicare population, which have been approved over the last 2 years. The commenter stated there are a limited number of recently approved highly innovative products for the ESRD patient population and encouraged CMS to grant as much flexibility as possible related to the FDA marketing authorization date.

However, a non-profit provider association stated that a prospective, rather than retrospective, date is appropriate, since part of the basis for providing additional payment is to spur innovation, which industry stakeholders have said has been thwarted.

Response: After careful consideration of these comments, we have decided to finalize the proposed definition of new to mean granted marketing authorization by FDA on or after January 1, 2020. While we appreciate that manufacturers of renal dialysis equipment and supplies that were granted FDA marketing authorization in prior years would want these products to be eligible for the TPNIES, our goal is not to provide a payment adjustment for all the products that have received FDA marketing authorization or for products that have had limited market uptake, but rather to establish an add-on payment adjustment for certain new and innovative products in order to support uptake by ESRD facilities of new and innovative renal dialysis equipment and supplies. In addition, we appreciate the complex issues the commenters raised if we were to select an earlier FDA marketing authorization date, and believe our approach will avoid the need to address those issues. We note that the ESRD PPS is a prospective payment system, in which changes are generally made prospectively, including eligibility requirements for add-on payment adjustments. In addition, this marketing authorization date of January 1, 2020 or later is consistent with the TDAPA's definition of a new renal dialysis drug or biological product.

Comment: Many commenters recommended that all FDA marketing authorizations under the PMA, De Novo, and 510(k) products that represent SCI should be eligible to receive the TPNIES. Given the shortage of new and innovative technologies in this disease area and the many differences between dialysis care and acute hospital services that often receive NTAP payment, they recommended that CMS consider deeming FDA's marketing authorization under the PMA or De Novo pathways as a criterion that would meet the SCI requirement. Additionally, they recommended adding a policy that would allow all approved and cleared FDA Breakthrough Therapy Designation products to meet the criteria.

A device manufacturers association and a device manufacturer and others made a similar

recommendation based on their concern that the requirement that all products undergo the SCI determination process will delay patient access to needed therapies. They pointed out that products that receive FDA marketing authorization under the PMA or De Novo pathways must undergo more stringent regulatory review and provide FDA with more data than a 510(k) submission and have demonstrated a level of clinical effectiveness and newness that products cleared under the 510(k) process have not.

They believe that this policy modification would have a negligible effect on the cost of the TPNIES program to the Federal Government, but it would have a tremendous effect on encouraging innovation. The commenters pointed out that no new devices for use in an ESRD facility were authorized by the FDA under a PMA or De Novo application from 2013 to 2017.

A medical technology company agreed, recommending that we allow devices, including capital equipment, that have made significant improvements upon an existing approved device be eligible for the TPNIES when delivering product updates that meet SCI or patient preference criteria. The company stated that this approach would encourage significant innovation that is achievable in a relatively short time period, reaching today's patients.

However, MedPAC stated that CMS should not use FDA's marketing authorization processes, including PMA and De Novo pathways, as a proxy for or in place of the proposed SCI criteria. They maintain that the Medicare program, not the FDA, should adjudicate spending determinations based on the specific needs of the Medicare population. MedPAC stated that FDA's role in the drug and device development process as a regulator is distinct and separate from the role of CMS as a payer. MedPAC noted that FDA regulates whether a device or pharmaceutical is "safe and effective" for its intended use by consumers. The FDA marketing authorization process may or may not include the new device or pharmaceutical's safety or

effectiveness with regard to the Medicare population.

MedPAC also pointed out that there have been many examples where devices approved through expedited FDA marketing authorization have not resulted in improvements in care relative to existing technologies, and in fact many have been recalled.

Response: In the CY 2020 ESRD PPS proposed rule, we referenced the SCI criteria in § 412.87(b)(1) and did not propose the alternative pathway described in § 412.87(c) which includes devices that have FDA marketing authorization and are part of FDA's Breakthrough Devices Program (which can include De Novo and PMA) that is deemed to meet the conditions specified in § 412.87(b)(1), that is, the SCI criterion. For this reason, we are unable to adopt this change in this final rule. In addition, we believe that instead of limiting eligibility for the TPNIES to PMA and De Novo as several commenters suggested, the SCI policy will provide an opportunity for a product that has no predicate product, that is, is not the first of its kind but offers SCI, to receive the TPNIES. Additionally, with regard to the comment regarding SCI delaying patient access to therapies, we believe that this is balanced with our opportunity to review more applications for TPNIES eligibility which may lead to more treatment choice for patients.

Comment: A device manufacturers association and 2 device manufacturers stated that CMS should finalize the proposal to adopt the IPPS SCI criteria specified including modifications finalized in future IPPS rules. They pointed out that on August 2, 2019, in the FY 2020 IPPS final rule, CMS finalized changes to the SCI criteria so that manufacturers can now present a wider variety of information to support the NTAP application. These changes were made to introduce greater flexibility in the SCI decision making process. Although they believe that adoption by reference is implied, they recommended that CMS explicitly adopt the new SCI

criteria in the final rule and, ultimately, in the TPNIES application itself.

Response: We acknowledge that revised criteria for assessing SCI was published in the FY 2020 IPPS final rule (84 FR 42180 through 42181). In accordance with the proposed reference to § 412.87(b)(1), which we are finalizing in new § 413.236(b)(5), we have adopted the FY 2020 IPPS changes to the SCI criteria, and any future changes to the SCI criteria, by reference, unless and until we make any changes to the criteria through notice and comment rulemaking.

Specifically, CMS will use the following criteria to evaluate SCI for purposes of the TPNIES under the ESRD PPS (see § 412.87(b)(1) and § 413.236(b)), based on the IPPS SCI criteria and related guidance:

A new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, and most importantly, the totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means:

• The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or

• The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers

the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or

• The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or,

• The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the U.S. or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

Comment: An LDO recommended that CMS finalize its proposal to adopt SCI as an eligibility criteria for the TPNIES, clarify and provide further guidance on how it intends to apply the new criteria, and establish a process that includes at least one reviewer of TPNIES applications with clinical expertise in ESRD care.

Response: We intend to establish a workgroup of CMS medical and other staff to review the studies and papers submitted as part of the TPNIES application, the public comments we receive, and the FDA marketing authorization and HCPCS application information and assess the extent to which the product provides SCI over current technologies. Our intent is to obtain input from a nephrologist along with other subject matter experts throughout our decision making process for determining TPNIES eligibility.

Comment: Several commenters, including a patient advocacy organization, a medical technology company, and a medical technology association requested that CMS expand on the SCI criteria for the TPNIES to include patient preference data, and clarify at least some of the elements that would be considered as improved quality of life. The commenters noted that the Kidney Health Initiative Renal Replacement Therapy Roadmap outlines the elements that should constitute improved quality of life for patients and they believe CMS should include and apply these elements in the CY 2020 ESRD PPS final rule. They also recommended that patient

preference data should be considered for evaluating SCI. They stated that it is critically important for TPNIES approvals to reflect the preferences of ESRD patients and empower their choice to do home dialysis or self-care. The organization offered to work with CMS to define a process for evaluating improvements in one or more activities of daily living and improved quality of life. The organization stated that such a process is especially important because patient preference and patient reported outcome data are not always available at the time that marketing authorization is granted by FDA. They want to ensure that equipment or supplies that represent a meaningful advance for ESRD patients, but where the patient's preferences have not yet been formally evaluated at the time of FDA marketing authorization, would be eligible for TPNIES.

Response: As stated in section II.B.1.a of the CY 2020 ESRD PPS proposed rule (84 FR 38354), since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we believe the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under the ESRD PPS. We intend to study in the future how patient preference information could be used to inform SCI determinations under the ESRD PPS to determine if we should establish any criteria that are specific to the ESRD PPS. In the interim, since TPNIES applications will be described in the annual ESRD PPS proposed rules, we urge ESRD patients and patient advocacy organizations to provide the patient perspective on the TPNIES applications in comments on the proposed rule. We note that the CMS determinations on the TPNIES applications will be issued in the annual ESRD PPS final rules based on the totality of the information provided, including public comments receiving during the rulemaking process.

Comment: A health services company pointed out that CMS did not provide a definition

for commercially available and asked that we eliminate the requirement in the final rule. The company pointed out that neither the IPPS add-on payment nor OPPS pass through payment rules require that the equipment or supply be commercially available and the CY 2020 ESRD PPS proposed rule provided no rationale for including this eligibility requirement.

Response: We included the eligibility requirement that a new and innovative renal dialysis equipment or supply be commercially available for the reasons set forth below, not to be consistent with the IPPS NTAP or OPPS pass-through payment. Regarding the request that we define commercially available, we are clarifying that commercially available means available for sale to ensure that manufacturing or other delays do not significantly delay patient access to the new equipment or supply.

We expect that if an application for the TPNIES is submitted by February 1, 2020 for the equipment or supply, the equipment or supply would be available to be sold by January 1, 2021, when the TPNIES period begins, if we determine the item is eligible. In addition, we note that the TPNIES period for a product begins on January 1 and ends 2 years later on December 31. We would expect that manufacturers would want to capitalize on the marketing opportunity available during the TPNIES period and ensure that the equipment or supply is commercially available on January 1. We are concerned that if the equipment or supply is not commercially available on January 1, there may be confusion from ESRD facilities over when the TPNIES period starts and ends. Therefore, we believe this is an important criteria for eligibility for the TPNIES. If the equipment or supply is not commercially available on January 1, the manufacturer would not meet one of the eligibility criteria for TPNIES and no TPNIES payments should be made. For this reason, we expect for the manufacturer to notify CMS by September 1 if the equipment or supply will not be commercially available by January 1. If the manufacturer

is unable to have market availability by January 1, 2021, the equipment or supply is not eligible for TPNIES in CY 2021.

Final Rule Action: After consideration of public comments, for CY 2020 we are finalizing the addition of § 413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies, with 5 modifications. First, we are clarifying that applicants must receive FDA marketing authorization by September 1 and not February 1; second, we are clarifying what commercially available means and when it needs to occur; third, we are clarifying when the HCPCS application needs to be submitted; fourth, we are clarifying what particular calendar year means; and fifth; we are taking out the reference to the application of the TPNIES in the calculation of the per treatment payment amount because we do not believe it is necessary in light of our changes to § 413.230. We are finalizing the addition of § 413.236(a) to state that the basis for the TPNIES is to establish an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD PPS under the authority of section 1881(b)(14)(D)(iv) of the Act.

We also are finalizing the addition of § 413.236(b) to state that a renal dialysis equipment or supply meet the following eligibility criteria in order to receive the TPNIES: (1) has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) and related guidance, and (6) is not a capital-related asset that an ESRD facility

has an economic interest in through ownership (regardless of the manner in which it was acquired).

We are also finalizing the addition of § 413.236(c) to establish a process for the TPNIES determination and deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. That is, we are finalizing that we will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. We are finalizing that we will only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the payment adjustment would take effect, and that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year.

ii. Pricing of New and Innovative Renal Dialysis Equipment and Supplies

In the CY 2020 ESRD PPS proposed rule (84 FR 38355), we stated that, with respect to the new and innovative renal dialysis equipment and supplies, we were not aware of pricing compendia currently available to price these items for the transitional add-on payment adjustment proposal discussed in this section. We also noted that, unlike new renal dialysis drugs and biological products eligible for the TDAPA, ASP and WAC pricing do not exist for renal dialysis equipment and supplies. Unlike the IPPS NTAP methodology, which uses MS-DRG payment and cost-to-charge ratios in its high cost criteria payment calculation, the ESRD PPS has a single per treatment payment amount. Therefore, we proposed to establish a pricing method in the absence of data indicating a true market price.

In accordance with ESRD billing instructions of the Medicare Claims Processing Manual (chapter 8, section 50.3), we proposed that ESRD facilities would report the HCPCS code, when

available, and their corresponding charge for the item. We explained that, in accordance with the Provider Reimbursement Manual (chapter 22, section 2203), Medicare does not dictate a provider's charge structure or how it itemizes charges but it does determine whether charges are acceptable for Medicare purposes. Charges should be reasonably and consistently related to the cost of services to which they apply and are uniformly applied. In addition, the Provider Reimbursement Manual (chapter 22, section 2202.4) specifies that charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients' charges used in the development of apportionment ratios should be recorded at the gross value; that is, charges before the application of allowances and discounts deductions.

Since we require charges to be reported at the gross value, we did not propose to use charges as the basis of payment. The ESRD PPS does not have a charge structure or a gap-filling policy similar to the DMEPOS policy. As a result, we proposed to obtain a pricing indicator that requires the item to be priced by Medicare Administrative Contractors (MACs). We proposed to adopt a process that utilizes invoiced-based pricing. We noted that there are instances in which invoice pricing is also used for DMEPOS. Specifically, in the Medicare Claims Processing Manual (chapter 23, section 60.3), we state that "potential appropriate sources for such commercial pricing information can…include verifiable information from supplier invoices."

In addition, we noted that in the CY 2019 Physician Fee Schedule final rule (83 FR 59663), we discussed that invoice based pricing is used to pay for Part B drugs and biologicals in certain circumstances as described in the Medicare Claims Processing Manual (chapter 17,

section 20.1.3). For example, if a payment allowance limit for a drug or biological is not included in the quarterly ASP Drug Pricing File or Not Otherwise Classified Pricing File, MACs are permitted to use invoice pricing. MACs may also use invoice based pricing for new drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified Pricing File. The new drug provision may be applied during the period just after a drug is marketed, that is, before ASP data has been reported to CMS. We stated that we believed using invoices for new drugs and drugs without national pricing is a similar situation to addressing new and innovative renal dialysis equipment and supplies that do not have a national price.

We stated that we believed that an invoice-based approach could be applied to the renal dialysis equipment and supplies that are the focus of our proposal. As noted previously, ESRD facility charges are gross values; that is, charges before the application of allowances and discounts deductions. We stated that we believed the MAC-determined price should reflect the discounts, rebates and other allowances the ESRD facility (or parent company) receives. These terms are defined in the Provider Reimbursement Manual (chapter 8).[32] If the MAC-determined price does not reflect discounts, rebates and other allowances, the price would likely exceed the facility's cost for the item and result in higher co-insurance obligations for beneficiaries. For this reason, we noted that it is important for MACs to develop a payment rate taking into consideration the invoice amount, the facility's charge for the item on the claim, discounts, allowances, rebates, the price established for the item by other MACs and the sources of information used to establish that price, payment amounts from other payers and the information used to establish those payment amounts, and information on pricing for similar items used to

32 Medicare Provider Reimbursement Manual. Chapter 8. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R450PR1.pdf.

develop a payment rate. We explained that we believe the information that ESRD facilities would supply to the MACs should be verifiable, so that we can more appropriately establish the actual facility cost of the items.

Under our proposal, the specific amounts would be established for the new and innovative renal dialysis equipment or supply HCPCS code using verifiable information from the following sources of information, if available: the invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We stated that once there is sufficient payment data across MACs, we would consider establishing a national price for the item through notice and comment rulemaking. We invited public comment on this proposed approach for pricing new and innovative renal dialysis equipment and supplies for the transitional add-on payment adjustment proposal discussed in section II.B.3.b.iii of this final rule. We also solicited comment on other pricing criteria and other verifiable sources of information that should be considered.

To mitigate the Medicare expenditures incurred as a result of the TPNIES proposal discussed later in this section of the final rule, we proposed to base the additional payment on 65 percent of the MAC-determined price. We noted that in the FY 2020 IPPS proposed rule (84 FR 19162) a 50 percent capped add-on amount was considered low with regard to providing hospitals with a sufficient incentive to use the new technology. In that rule, we proposed to modify the current payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent. In the FY 2020 IPPS final rule (84 FR 42048), the percentage was revised

to be 65 percent. In the CY 2020 ESRD PPS proposed rule (84 FR 38356), we stated we believed that we have the same goal as IPPS with regard to supporting ESRD facility use of new and innovative renal dialysis equipment and supplies. Therefore, we proposed to base the TPNIES on 65 percent of the MAC-determined price. We also solicited comment on whether we should explicitly link to the IPPS NTAP mechanism's maximum add-on payment amount percentage so that any change in that percentage would also change for the proposed TPNIES paid to ESRD facilities for furnishing new and innovative renal dialysis equipment and supplies.

iii. Proposed Use of a Transitional Add-on Payment Adjustment for New and Innovative Renal Dialysis Equipment and Supplies

In the CY 2020 ESRD PPS proposed rule, we acknowledged that ESRD facilities have unique challenges with regard to implementing new renal dialysis drugs and biological products as discussed in section II.B.1.b of this final rule, and we stated that we believed that the same issues would apply with respect to incorporating new and innovative equipment and supplies into their standards of care. For example, when new and innovative equipment and supplies are introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies 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 product and its effect on patient outcomes. We stated that we believed this uptake period would be supported by the proposed TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS. The proposed TPNIES would target payment for the use of new and innovative renal dialysis equipment and supplies during the period when a product is

new to the market.

We proposed to apply the TPNIES for 2-calendar years from the effective date of the change request, which would coincide with the effective date of the CY ESRD PPS final rule. We also proposed that after the TPNIES period ends, the item would become an eligible outlier service as provided in § 413.237. Therefore, we proposed revisions to § 413.237(a)(1) to reflect outlier eligibility for the new renal dialysis equipment or supply once the TPNIES period ends. We stated that we believed that 2 years would be a sufficient timeframe for ESRD facilities to set up or adjust business practices so that there is seamless access to the new and innovative equipment and supplies. In addition, historically when we have implemented policy changes whereby facilities need to adjust their system modifications or protocols, we have provided a transition period. We noted that we believed that this 2-year timeframe is similar in that facilities are making changes to their systems and care plans to incorporate the new renal dialysis equipment and supplies into their standards of care and this could be supported by a transition period.

Further, we stated that we believed providing the TPNIES for 2 years would address the stakeholders' concerns regarding additional payment to account for higher cost of more new and innovative equipment and supplies that they believe may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, the TPNIES would give the new and innovative equipment and supplies a foothold in the market so that when the timeframe is complete, they are able to compete with the other equipment and supplies also accounted for in the ESRD PPS base rate. Once the 2-year timeframe is complete, we proposed that the equipment or supply would then qualify as an outlier service, if applicable, and the facility would no longer receive the TPNIES for that particular item. Instead, in the outlier policy space, there

is a level playing field where products could gain market share by offering the best practicable combination of price and quality.

We noted that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary co-insurance, since we have not previously provided a payment adjustment for renal dialysis equipment and supplies in the past. However, to support agency initiatives and to be consistent with both our TDAPA policy and IPPS payment policies, we noted that we believed that the proposed TPNIES would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment and supplies.

We stated that the intent of the TPNIES would be to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative equipment and supplies. We explained that, at this time, we do not believe that it would be appropriate to add dollars to the ESRD PPS base rate for new and innovative renal dialysis equipment and supplies because, as noted previously, the ESRD PPS base rate includes the cost of equipment and supplies used to furnish a dialysis treatment. As we have stated in CY 2019 ESRD PPS proposed rule (83 FR 34314), we believe that increasing the base rate for these items could be in conflict with the fundamentals of a PPS. That is, under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average cost and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's resource use which creates an incentive for facilities to control their costs. It is not the intent of a PPS to add dollars to the base rate whenever a new product is made available.

Therefore, we also proposed to add § 413.236(d) to provide a transitional add-on

payment adjustment for new and innovative renal dialysis equipment or supply based on 65 percent of the MAC-determined price, as described in proposed § 413.236(e). The TPNIES would be paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate would not be modified and the new and innovative renal dialysis equipment or supply would be an eligible outlier service as provided in § 413.237.

We also proposed to add § 413.236(e) to require that the MAC on behalf of CMS would establish prices for the new and innovative renal dialysis equipment and supplies described in newly added § 413.236(b), and that we would use these prices for the purposes of determining the TPNIES. The specific amounts would be established for the new and innovative renal dialysis equipment or supply HCPCS code using verifiable information from the following sources of information, if available: the invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We also proposed to add paragraph (e) to § 413.230, Determining the per treatment payment amount, to reflect the TPNIES. We stated that we believed this modification is necessary so the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount.

Since we were proposing to add paragraphs (d) (discussed in section II.B.1.e of this final rule) and (e) to § 413.230, we also proposed a technical change to remove “and” from the end of § 413.230(b). We proposed that the “and” would be added to the end of § 413.230(d).

In addition, we proposed to revise the definition of ESRD outlier services at

§ 413.237(a)(1) by adding a new paragraph (a)(1)(v) to include renal dialysis equipment and supplies that receive the TPNIES as specified in § 413.236 after the payment period has ended. We proposed to redesignate existing paragraph (a)(1)(v) as paragraph (a)(1)(vi) and revise the paragraph to state "As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services." We proposed this technical edit to reflect an order in the definition of ESRD outlier services as first, items and services included and second, items and services that are excluded.

We also proposed technical changes to § 413.237(a)(1)(i) through (iv) to replace the phrases "ESRD-related" and "used in the treatment of ESRD" with "renal dialysis" to reflect the current terminology used under the ESRD PPS and to replace the word "biologicals" with "biological products" to reflect FDA's preferred terminology.

The comments and our responses to the comments on our proposals regarding pricing of new and innovative renal dialysis equipment and supplies and the proposed changes to ESRD PPS regulations are set forth below. We did not receive comments on our proposal to add paragraph (e) to § 413.230 to reflect the TPNIES, for a technical change to remove "and" from the end of § 413.230(b), for a technical change to include "and" to the end of § 413.230(d), or the technical changes to § 413.237(a)(1)(i) through (iv) to replace the phrases "ESRD-related" and "used in the treatment of ESRD" with "renal dialysis" to reflect the current terminology used under the ESRD PPS and to replace the word "biologicals" with "biological products" to reflect FDA's preferred terminology. We are therefore finalizing these revisions to the regulation text as proposed.

Comment: Most commenters, including a national dialysis stakeholder organization, an LDO, a nursing association, a device manufacturers association and a patient advocacy

organization expressed concern that after the 2-year TPNIES period, we did not propose to make changes to the base rate. Rather, we proposed to make these items eligible for outlier payments. Several commenters asked that CMS adjust the base rate to include dollars for the incremental difference of the cost of the new device and what may be reflected in the ESRD PPS base rate already. They asserted that this comprehensive approach is the best way to align the TPNIES policy with the President's goal to incentive the adoption of new innovations in the ESRD program. In addition, MedPAC stated that CMS should not make duplicative payments for new ESRD-related equipment and supplies by paying under the TPNIES for 2 years and paying for an item with a similar purpose or use that is already paid under the ESRD PPS base rate. For example, CMS could reduce the TPNIES payment amount to reflect the amount already included in the base rate. An LDO also made this suggestion.

The LDO suggested that CMS should apply funds not expended under the narrower TDAPA eligibility policy to make ESRD PPS adjustments when it adds new products to the ESRD PPS base rate. An adjustment could be established that equals the incremental difference between any amounts associated with the functional category currently in the base rate attributable to the new product's cost. The LDO noted that this might result in CMS adding the product's full cost if the base rate does not include any such reimbursement or a lesser amount that reflects current dollars in the base rate. The LDO also recommended that CMS make similar adjustments to ensure that the base rate reflects costs associated with a new device after a TPNIES ends.

A device manufacturer suggested that, at the end of the TPNIES period, CMS positively adjusts the ESRD PPS base rate to reflect the added value of the TPNIES product. For example, CMS could adjust the ESRD PPS via a value-based modifier adjustment by exercising its

authority under section 1881(b)(14)(D)(iv) of the Act to adjust payments under the ESRD PPS for value-enhancing medical products following the expiration of the transitional pass-through period. The value-based modifier could be derived from the demonstrated value of a given TPNIES product—for example, a device's demonstrated impact on averting hospitalizations and other additional resources. The manufacturer suggested that value could be shared between facilities using the new device and the Medicare program.

The patient advocacy organization expressed concern that by leaving a funding "cliff" at the end of the 2-year TPNIES period, clinics may not test new products. The organization also expressed concern that if the device reduces complications and thereby reduces the total cost of care for ESRD patients, but that these savings are not reflected in the fee-for-service (FFS) payment system, the device will be offered to Medicare Advantage enrollees but not to FFS beneficiaries.

Another commenter recommended collection of use data similar to that collected under the TDAPA policy for new renal dialysis drugs and biological products that are in new ESRD PPS functional categories, and if a product is used by a sufficient proportion of Medicare beneficiaries, CMS should increase the ESRD PPS base rate.

A national dialysis association, a device manufacturers association and a device manufacturer also recommended that at the end of the TPNIES period, CMS positively adjust the ESRD PPS base rate to reflect the added value of the TPNIES product. The commenters stated that failure to positively adjust the ESRD PPS base rate after the TPNIES period will result in a situation where providers must absorb the costs of the new product after the expiration of the add-on payment adjustment. This could discourage providers from adopting the new device in the first instance or from using the device for the long-term. The commenters noted that both

outcomes would hinder innovation and stall improvements in patient care, which undercuts the fundamental purpose of the TPNIES. The organization stated that the outlier pool was never designed to provide comprehensive reimbursement for new, high-cost products to a significant number of beneficiaries. The outlier pool cannot function as a substitute for thoughtfully building dollars into the base rate to cover expected care.

An LDO disagreed that it would be inappropriate to add new dollars to the ESRD PPS base rate at the end of the TPNIES timeframe. The LDO is concerned that the TPNIES will encourage uptake of high-cost new technologies and then leave providers without a way to cover the costs above the amount accounted for in the base rate after the 2-year window closes. The LDO stated that the outlier policy does not address this funding shortfall and would exclude lower cost innovative supplies that do not exceed the FDL threshold. In addition, although the LDO has longstanding concerns with the outlier mechanism, the LDO agreed that device technologies (like drugs) should be part of the outlier payment mechanism, as they are for other Medicare providers, to address individual high cost cases.

While the LDO agrees that it is not the intent of the PPS to add new money whenever something new is made available, the LDO expressed concern that the current policy does not leave CMS any flexibility to do so when appropriate and is a significant disincentive for technology developers to enter the ESRD space. The LDO recommended that CMS establish a process for adding dollars into the base rate, where appropriate, to ensure PPS payments are sufficient to reflect improved technologies once the TPNIES timeframe ends. In addition, CMS should finalize its proposal to add TPNIES-eligible products to its definition of ESRD outlier services to account for individual high cost cases.

Response: We appreciate the concerns raised by the stakeholders with regard to our

proposal to not adjust the ESRD PPS base rate after the end of the TPNIES period. As we explained in the CY 2020 ESRD PPS proposed rule, sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. When implementing the ESRD PPS for CY 2011, we used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate (75 FR 49075). Therefore, we believe the ESRD PPS base rate currently reflects the renal dialysis equipment and supplies that will be eligible for TPNIES.

Moreover, as we have explained with respect to the TDAPA for drugs already reflected in the ESRD PPS functional categories, we believe adding dollars to the ESRD PPS base rate for items that are already reflected in the ESRD PPS base would be inappropriate and 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 rate whenever something new is made available. Additionally, the statute does not require that we add dollars to the ESRD PPS base rate when a new item is available.

With regard to the comment about CMS using a value-based modifier adjustment, as we explained in the CY 2020 ESRD PPS proposed rule, the intent of the TPNIES for new and innovative equipment and supplies is to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative equipment and supplies. For example, when new and innovative equipment and supplies are

introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies 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 product and its effect on patient outcomes. We believe this uptake period would be supported by the TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS.

We appreciate the suggestion of reducing the TPNIES payment by the amount already included in the ESRD PPS base rate, however, ESRD facilities have historically not reported on claims the utilization of composite rate items and services, which is what these products are considered to be. Therefore we do not have the data sufficient to make these calculations at this time. We note that we included a request for this information in section VIII.A of the CY 2020 ESRD PPS proposed rule on how to collect this data. In response some commenters stated that the composite rate components to price the cost of dialysis treatment was outmoded and unnecessary concept and counter to the objective of the bundled system instituted with the ESRD PPS in CY 2011.

We are concerned about the comment stating that ESRD facilities will choose to not adopt new and innovative equipment and supplies. We do not agree with these commenters because we believe that innovative products that are competitively priced and that add value will be able to be successfully marketed and that ESRD facilities will want to use them. In addition, since we collect monitoring data, we will be aware of utilization and behavior trends and will be able to use this data to inform future policies.

Comment: Most provider organizations including a national dialysis stakeholder organization, an LDO, a professional association, a nursing association and a national dialysis association requested that we provide the TPNIES for 2-full calendar years of cost and utilization data. They stated that patients and providers take time to integrate new technologies and innovation into ongoing care practice. To ensure that cost and utilization data are accurate, they recommended that CMS extend the TPNIES period for the time required to collect 2 full years of cost and utilization data.

However, a device manufacturer association and a medical technology company requested that we extend the TPNIES period to 4 years. They opined that a 2-year period would discourage small start-up companies from developing innovative equipment and supplies, as building the support and distribution infrastructure nationwide to support new technology implementation takes far longer. They stated that extending the coverage period to 4 years would help level the playing field between small innovators and large, global manufacturers with an existing support and distribution footprint. Several other commenters recommended a 3-year TPNIES period because facilities need several years to set up system modifications and adjust business practices. They stated they believe that at least 3 years is an appropriate timeframe based on CMS' experience with other new technology add-on payment mechanisms.

Response: In providing an add-on payment, that is, the TPNIES, for new and innovative renal dialysis equipment and supplies that are accounted for in the ESRD PPS base rate, we did not propose to incorporate these products into the ESRD PPS base rate when the TPNIES period ends. The purpose for the TPNIES is to provide a transition period for the unique circumstances experienced by ESRD facilities when incorporating certain new and innovative equipment and supplies into their businesses and to allow time for the uptake of the new and innovative

equipment and supplies. For example, when new and innovative renal dialysis equipment and supplies are introduced to the market, ESRD facilities would need to analyze their budgets and engage in contractual agreements to accommodate the new items into their care plans. Newly marketed equipment and supplies 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 product and its effect on patient outcomes. We believe this uptake period would be supported by the TPNIES because it would help facilities transition or test new and innovative equipment and supplies in their businesses under the ESRD PPS. The TPNIES would target payment for the use of new and innovative renal dialysis equipment and supplies during the period when a product is new to the market.

Further, we believe that the 2-year period gives the ESRD facility the opportunity to incorporate the product into their business model if they choose. The facility would be comparing a product currently in use with a new and innovative product and making a choice if the increased cost would be commensurate with increased clinical value to the beneficiary. We continue to believe providing the TPNIES for 2 years is appropriate for new and innovative products and that a longer timeframe to establish the product's uptake is not necessary, particularly since the ESRD PPS base rate includes money for these products. We are not expanding the duration of the TPNIES period because we believe that 2 years strikes the appropriate balance of supporting innovation while protecting the Medicare expenditures. We note that the TPNIES period begins on January 1, the effective date of the annual ESRD PPS final rule in which we announce our determinations with regard to TPNIES applications, and ends on December 3l, that is, 2 years later.

Comment: Many comments expressed support for the proposal to base payment for the

TPNIES on the price established by the MACs using information from invoices and other relevant sources of information. However, MedPAC expressed support for the proposal but only for the first 2-calendar quarters after CMS begins applying the TPNIES. Thereafter, MedPAC recommended that CMS should set the price of new equipment and supplies using a method based on pricing data collected directly from each manufacturer, similar to how CMS establishes the average sales price (ASP) for Part B drugs.

The Commission pointed out that the ASP for a Part B drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. There is a 2-quarter lag in the data used to set ASP-based payment rates. MedPAC stated that an approach similar to how CMS collects ASP data would increase the consistency of pricing data and should lead to more accurate payment rates for items paid under the TPNIES. In establishing a process for collection of average sales price data for equipment and supplies, the Commission recommended that, similar to the TDAPA for new renal dialysis drugs and biological products, CMS should link payment of the TPNIES to a requirement that equipment and supply manufacturers submit ASP-like data to CMS.

Other commenters, including a device manufacturer, a device manufacturers association, and a patient advocacy organization recommended that, instead of the invoice-based pricing process at the MAC level, with possible national-level rates set once there is enough data across multiple MACs, CMS adopt a rate determination process like the NTAP. Under this process, TPNIES applicants, when providing SCI data and other information in their application, can also provide information on the cost of the product. Then, when CMS discusses the application in the

ESRD PPS proposed rule, CMS could discuss the cost information provided by the applicant and ask stakeholders (including providers, innovation leaders and patient-centered advocacy organizations) for comments. The national payment rate could then be finalized in the ESRD PPS final rule when CMS accepts or denies the TPNIES application. The commenters indicated that this change in process would elevate the principle and practice transparency and provide far greater certainty for ESRD providers and, more importantly, limit the impact of the TPNIES administrative process on patient access.

A national dialysis stakeholder organization and an LDO asked that CMS ensure that the pricing for the TPNIES is transparent and provides predictability and consistency in pricing. A professional association stated that by their very nature, MACs make local coverage and reimbursement decisions that can vary by region. To ensure consistency and adequacy in pricing and reimbursement, they urged CMS to ensure that the proposed MAC pricing process is transparent and understandable for all stakeholders. Another LDO agreed and requested that CMS specify in the CY 2020 ESRD PPS final rule that MACs must disclose the sources of information relied on (without disclosing proprietary information) so stakeholders can understand the basis for pricing determinations as well as any variations in prices jurisdictions.

A national dialysis association recommended that the MACs should use a transparent, notice-and-comment process in order to establish the reimbursement associated with the TPNIES. The association stated that if the MACs cannot accommodate a notice-and-comment process, then CMS should consider an alternative process for the establishment of reimbursement policy that would ensure the opportunity for notice-and-comment to the public.

Response: As we stated in the CY 2020 ESRD PPS proposed rule, at this time, we do not have the data to set a price for new and innovative renal dialysis equipment and supplies. We

note that there are other times when items and services do not have fee schedule payment rates assigned to them that are paid under Medicare via a MAC-determined value, for example, when new drugs do not have an ASP. We agree with the commenters that transparency and predictability is important, however, we would need time to develop a national price for a particular product. We note that in comparison to IPPS's NTAP policy, we do not apply the ESRD PPS outlier policy during the TPNIES period, which makes process we have laid out for determining the price more predictable than the IPPS. With regard to MedPAC's suggestion for an ASP-like data reporting system, we do not have sufficient data at this time to develop such a system, but will take the comment into consideration for future rulemaking.

With regard to the comments that we rely solely on the manufacturer's estimated cost to the facility and public comments to establish a national payment amount for a TPNIES equipment or supply, we are requesting that manufacturers estimate the cost of the equipment or supply to the facility on a per treatment basis in the application. However, while we believe this information from the manufacturer is one factor in the MAC price determination process, we do not believe it would be appropriate to set a national price based solely on that information. As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38355), the MAC-determined price would be established using verifiable information from the following sources of information, if available: the invoice amount, facility charges for the item, discounts, allowances, and rebates; the price established for the item by other MACs and the sources of information used to establish that price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant.

We did not propose to establish a national price because we do not have historical cost

data and we are only in the initial phases of developing a process to evaluate cost criteria. However, we will consider this idea for future rulemaking.

Comment: While most commenters expressed support for the TPNIES proposal to pay 65 percent of the MAC-determined price, an organization of LDOs and an LDO suggested that CMS consider whether or not the innovation replaces a product currently reflected in the ESRD PPS base rate and take a more customized approach in establishing a product's TPNIES amount. They also stated that the proposed TPNIES payment of 65 percent of prices obtained from invoices or other relevant data sources might be sufficient for a product that replaces one included in the ESRD PPS bundled payment. However, they noted it will likely fall short in covering the costs of a completely new and innovative product. The commenters stated that with ESRD facilities' negative margins, facilities will have little room to absorb these costs, which will compromise the adoption of, and beneficiaries' access to, truly innovative products. They further stated that it is possible that for new devices, 65 percent of the MAC-determined price will sufficiently cover facility costs. They asked that CMS monitor this policy and leave open the possibility of amendments, as needed, to ensure that clinically valuable, new technology can actually reach beneficiaries.

A device manufacturer and a device manufacturers association and others urged CMS to pay 100 percent of the cost of the new product to ensure maximum adoption of the new TPNIES product, and to compensate for any unforeseen costs associated with that product. The commenters stated that the ESRD PPS bundled payment for thrice-weekly dialysis care is a model that encourages efficiency among existing services and inputs but discourages investment in new technologies that offer a new value proposition. They asserted that providing 65 percent of the known costs of the new device through TPNIES does not provide payment for any

unanticipated costs of the new technology such as additional staff training, product administration, or facility handling.

In addition, the commenters pointed out that there is a significant lag in payment that requires facilities to assume liability for any excess costs associated with a new device above the ESRD PPS bundled payment amount. Thus, the commenters opined that new devices create a dilemma for providers under the ESRD PPS: either absorb the costs associated with a new technology to advance the standard of care or forego the new technology despite its clinical benefits. For these reasons, they urged CMS to set the payment adjustment at 100 percent of the cost of the new TPNIES approved product.

However, MedPAC expressed support for the proposal to pay a reduced percentage of the new item's cost as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices. MedPAC also recommended that CMS not explicitly link the ESRD PPS TPNIES payment percentage to the IPPS NTAP mechanism's maximum add-on payment percentage. The Commission pointed out that CMS would have greater flexibility about any future changes to the ESRD PPS payment percentage if it was not explicitly linked to the IPPS payment percentage.

Response: We appreciate the support for the proposal to pay 65 percent of the MAC-determined price and agree with MedPAC that this would disincentivize high launch prices. At this time, we are not finalizing a policy to explicitly tie the ESRD PPS to future changes to the IPPS NTAP policy with regard to the IPPS NTAP mechanism's maximum add-on payment amount percentage. However, we believe that we have the same goal as the IPPS with regard to supporting ESRD facility use of new and innovative renal dialysis equipment and supplies. In addition, we agree with MedPAC that the TPNIES amount needs to be a value that is enough to

incentivize uptake of the new and innovative equipment or supply by ESRD facilities but believe that we need to balance this with sharing risk for the new product. We agree with commenters with regard to monitoring utilization of these products that are eligible for the TPNIES and we note that any future changes to this policy would be addressed through notice and comment rulemaking.

Comment: MedPAC stated that CMS should publish in the final rule an estimate of the increase in beneficiaries' and taxpayers' spending due to the proposed policy change and the method used to develop the estimate.

Response: As we explain in section X of this final rule, the fiscal impact of Medicare and beneficiary spending cannot be determined due to the uniqueness of the new renal dialysis equipment and supplies eligible for the TPNIES and their costs.

Final Rule Action: After consideration of public comments, for CY 2020 we are finalizing the addition of § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply based on 65 percent of the MAC-determined price, as described in newly added § 413.236(e). The TPNIES will be paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237.

We are also finalizing the addition of § 413.236(e) to require that the MAC on behalf of CMS will establish prices for the new and innovative renal dialysis equipment and supplies described in newly added § 413.236(b), and that we will use these prices for the purposes of determining the TPNIES. The MAC will use verifiable information from the following sources of information, if available: (1) the invoice amount, facility charges for the item, discounts,

allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

In addition, we are finalizing the proposed revision to the definition of ESRD outlier services at § 413.237(a)(1) by adding a new paragraph (a)(1)(v) to include renal dialysis equipment and supplies that receive the TPNIES as specified in § 413.236 after the payment period has ended. We are finalizing the redesignation of existing paragraph (a)(1)(v) as paragraph (a)(1)(vi) and the revision of the paragraph to state "As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services."

iv. Implementation Process for CY 2020

We intend to develop an electronic application for the TPNIES over the next year. In the meantime, in order to implement the TPNIES for CY 2020 and provide an opportunity for equipment and supply manufacturers to apply for TPNIES payment for CY 2021, we are providing in this final rule certain technical instructions for applications submitted in CY 2020. In addition, we will provide these instructions on a new CMS webpage under development for the TPNIES.

<u>Deadline</u>

Submit a complete application with a response to each question below no later than February 1, 2020. An application is considered complete when all of the information requested has been submitted by the date specified and when questions related to the submission have been answered by the applicant.

Address to send applications

Mail four copies of the completed applications to the following address:

ESRD PPS TPNIES Application

Division of Chronic Care Management

Centers for Medicare and Medicaid Services

M/S C5-05-07

7500 Security Blvd.

Baltimore, MD 21244-1850

Additionally, submit an electronic version of the application via email to ESRDPayment@cms.hhs.gov. Emailed versions of the materials must be compatible with standard CMS software such as Adobe Acrobat DC for 2015 or Microsoft Word 2010. The subject line of the email must say ESRD PPS TPNIES application. Total attachments in one email must not exceed 20 megabytes. If necessary, send multiple emails with attachments less than 20 megabytes. Questions pertaining to the TPNIES process may also be sent to the electronic mailbox noted above.

Required information

Applications must include a response to each question below. CMS may request other information to evaluate specific TPNIES requests. A separate application is required for each distinct equipment or supply included in the TPNIES request.

1, Name, address, telephone number, and email address for the primary and backup contact for the application. If using a consultant, provide a contact from the manufacturer in addition to the consultant's contact information.

2. Trade/brand name of the equipment or supply.

3. Describe the technology in general terminology -- What is it? What does it do? How is it used? Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-reviewed articles relevant to the new equipment or supply.

4. Have you submitted an application for pass-through payments under the Medicare outpatient prospective payment system or new technology payments under the IPPS? If so, please provide the tracking number or, if it was approved, please provide the date of approval.

5. Under what pathway are you seeking marketing authorization from FDA? What is the date of anticipated FDA marketing authorization for the equipment or supply? Provide a copy of the FDA marketing authorization. If marketing authorization has not yet been granted, provide a copy of the authorization to CMS immediately after it becomes available.

Per 42 CFR § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by September 1 prior to the beginning of the calendar year (CY) for which the TPNIES would be effective (for CY 2021 payment, not later than September 1, 2020).

6. List the name and telephone number or email address of a contact at FDA who is knowledgeable about the submission for marketing authorization for the new equipment or supply listed above.

7. Will the equipment or supply be available on the market immediately after FDA marketing authorization? If not, provide the date that the equipment or supply came on the market (that is, first sales or availability) and an explanation and documentation of any anticipated delay (for example, manufacturing issues or other reasons). If commercial availability has not yet occurred, provide proof of commercial availability to CMS immediately after it becomes available, for example, a manufacturer's bill of sale. Note that the manufacturer

must inform CMS by September 1 if the equipment or supply will not be available by January 1.

8. Is there an investigational device exemption number from the FDA assigned to the equipment or supply? If yes, please provide this code. Refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051480.htm for more details.

9. What class (I, II, or III) was/is assigned to the equipment or supply? Refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm for more details.

10. Has an application for an HCPCS code been submitted? If not, please note that submission of the HCPCS application is required by September 1, 2020, so that we are able to use information from the HCPCS application in our determination process. Refer to http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html for more information.

11. What is the anticipated cost of the equipment or supply to the ESRD facility, per treatment? Provide a breakdown of how the cost of the new equipment or supply is calculated.

12. What is the anticipated Medicare and Non-Medicare volume of this equipment or supply for the 2 years in the TPNIES period? Describe how you arrived at this estimate. This estimate should be based on the actual or projected sales of your equipment or supply, not the total population eligible for the equipment or supply.

Note: Applicants are not required to submit proprietary or confidential information as part of the application. However, an applicant may choose to include such information to support its request. Applicants should note that information they include in an application is not explicitly protected from disclosure in response to a Freedom of Information Act (FOIA) request. However, FOIA does include an exemption for trade secrets and commercial and financial

information obtained from a person that is privileged or confidential.

Once the information requested by CMS is received and reviewed, for equipment and supplies eligible for the TPNIES, we will issue a change request with billing guidance that will provide notice that the equipment or supply is eligible for the TPNIES as of January 1 and technical instructions on how to report the equipment or supply on the ESRD claim. This change request will initiate the TPNIES period and it will end 2 years from the change request's effective date.

c. Comment Solicitation on Payment for Renal Dialysis Humanitarian Use Devices (HUD)

Medical devices and related innovations are integral in meeting the needs of patients, especially the most vulnerable patients, such as ESRD patients and those with rare medical conditions. While FDA determines which devices are authorized for marketing, public healthcare programs such as Medicare determine how these products will be covered and paid, which can affect patient access to new and innovative products.

In the CY 2020 ESRD PPS proposed rule (84 FR 38357), we solicited comments on Medicare payment for renal dialysis services that have a Humanitarian Use Device (HUD) designation. Under FDA regulations (21 CFR 814.3(n)), a HUD is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year." We explained in the CY 2020 ESRD PPS proposed rule that Medicare has no specific rules, regulations or instructions with regard to HUDs. We noted that we were particularly interested in receiving comments on HUDs that would be considered renal dialysis services under the ESRD PPS, any barriers to payment encountered, and past experience in obtaining Medicare payment for these items through the MACs.

We received 7 comments on this solicitation. The comments and our response are set forth below.

Comment: We received comments from a device manufacturer, a medical device manufacturing association, a drug manufacturer, a non-profit provider, a professional society, a national dialysis stakeholder organization and a patient advocacy organization.

The commenters noted that in 1990, Congress created the HUD program to encourage the research, development and marketing of innovative devices for the treatment of rare diseases or conditions where no comparable devices are available to those patients. They stated that lack of Medicare reimbursement for HUDs impedes access to these treatments for Medicare beneficiaries. They also stated that CMS should ensure that HUDs are eligible for Medicare reimbursement, and suggested that a Congressional directive that HUDs be sold by manufacturers at cost indicates that CMS should establish Medicare payment for HUDs at invoice.

A medical device manufacturing association and a patient advocacy organization noted that there should be Medicare coverage of HUDs and payment for these devices under the ESRD benefit if such devices are required to be used in the ESRD facility, whether they are for the treatment of ESRD or for the treatment of other conditions related to renal dialysis.

A drug manufacturer noted its understanding that the HUD program is a specific FDA program, but encouraged CMS to work with the company and other innovators to protect access to innovative products that treat a disease or condition affecting a very small number of individuals in the U.S. annually. The company noted that drugs that are administered to a small percentage of patients cannot be accounted for properly in a bundled payment system. If dollars are allocated across all patients, then those who require the drug may not receive the care they

need because the providers administering it will not have sufficient funds, while those providers who do not provide the product will see a small increase in their base rate. The company stated that money should follow the patient in these circumstances to protect access to drugs that benefit a small number of patients.

A device manufacturer urged CMS to promulgate a regulation clarifying that HUDs are within the definition of renal dialysis services or dialysis services depending on the device's function, and explicitly define that HUDs should be reimbursed based on invoice given that Congress has already addressed the invoice price to be charged. A patient advocacy group urged CMS to ensure a reimbursement pathway for devices with a HUD designation.

Response: We appreciate the range of comments we received on this issue. We will consider these comments carefully as we contemplate future policies related to HUDs.

4. Discontinuation of the ESA Monitoring Policy (EMP) under the ESRD PPS

a. Background

In the CY 2011 ESRD PPS final rule (75 FR 49067, 49145 through 49147), CMS adopted the ESA monitoring policy (EMP) under the ESRD PPS for purposes of calculating the base rate and for establishing the outlier policy's percentage and thresholds.

For purposes of calculating the CY 2011 ESRD PPS base rate, payments for ESAs were capped based on determined dose limits as discussed in the Medicare Claims Processing Manual (chapter 8, section 60.4.1). Payments for epoetin alfa in excess of 500,000 units per month in 2007 were capped at 500,000 units and a similar cap was applied to claims for darbepoetin alfa, in which the caps were based on 1500 mcg per month in 2007 (75 FR 49067).

As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38357 through 38358) with regard to the application of the outlier policy, since ESAs are considered to be an ESRD

outlier service under § 413.237(a)(1)(i), covered units are priced and considered toward the eligibility for outlier payment consistent with § 413.237(b). That is, we apply dosing reductions and ESA dose limits consistent with the EMP prior to any calculation of outlier eligibility. Medicare contractors apply a 25 percent reduction in the reported ESA dose on the claim when the hemoglobin (or hematocrit) level exceeded a certain value, unless the ESRD facility reported a modifier to indicate the dose was being decreased. Also under the EMP, ESRD facilities are required to report other modifiers to indicate a patient's 3-month rolling average hemoglobin (or hematocrit) level so that the Medicare contractor knows when to apply a 50 percent reduction in the reported ESA dose on the claim. In addition to these dosing reductions, we apply ESA dose limits as discussed in the Medicare Claims Processing Manual (chapter 8, section 60.4.1) prior to any calculation of outlier eligibility.

When we adopted the EMP for the ESRD PPS in the CY 2011 ESRD PPS final rule, we explained that the continued application of the EMP would help ensure the proper dosing of ESAs and provide a safeguard against the overutilization of ESAs, particularly where the consumption of other separately billable services may be high, in order to obtain outlier payments (75 FR 49146). In the CY 2020 ESRD PPS proposed rule, we explained that due to implementation of the ESRD PPS and FDA relabeling of epoetin alfa, which stated that the individualized dosing should be that which would achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL, we no longer believed application of the EMP is necessary to control utilization of ESAs in the ESRD population. That is, the impact of no longer paying separately for ESAs, which discourages overutilization, along with practitioners prescribing the biological product to maintain a lower hemoglobin level, has resulted in a decline in its utilization and a stringent monitoring of the biological product's levels in patients.

b. Discontinuing Application of the EMP to Outlier Payments under the ESRD PPS

CMS proposed that, effective January 1, 2020, we would no longer apply the EMP under the ESRD PPS. As we explained in the CY 2020 ESRD PPS proposed rule, since the implementation of the ESRD PPS, ESA utilization has decreased significantly because the structure of the PPS removed the incentives to overuse these biological products. Under our proposal, ESRD facilities would no longer be required to report the EMP-related modifiers and Medicare contractors would no longer apply dosing reduction or dose limit edits to ESA dosing. Therefore, these edits would no longer be applied prior to calculation of outlier eligibility and would no longer be reflected in outlier payments.

We stated that we would continue to require ESRD facilities to report all necessary information for the ESRD Quality Incentive Program, and noted that, as part of managing the ESRD PPS, CMS has a monitoring program in place that studies the trends and behaviors of ESRD facilities under the ESRD PPS and the health outcomes of the beneficiaries who receive their care.[33] We stated that if we finalize this proposal, we would continue to monitor the utilization of ESAs to determine if additional medically unlikely edits are necessary. In addition, we noted that with the increased use of certain phosphate binders that have the secondary effect of anemia management, CMS would closely monitor ESA usage in conjunction with phosphate binder prescribing and usage.

We stated in the CY 2020 ESRD PPS proposed rule that we believed discontinuing this policy would reduce burden for ESRD facilities because the EMP provides an opportunity for appeal to address those situations where there might be medical justification for higher hematocrit or hemoglobin levels. Beneficiaries, physicians, and ESRD facilities are required to

[33] ESRD PPS Claims-Based Monitoring Program. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Claims-Based-Monitoring.html.

submit additional documentation to justify medical necessity, and any outlier payment reduction amounts are subsequently reinstated when documentation supports the higher hematocrit or hemoglobin levels. Thus, we explained that this proposal would reduce the documentation burden on ESRD facilities because they would no longer have to go through the EMP appeal process and submit additional documentation regarding medical necessity.

The comments and our responses to the comments on our proposal to discontinue the application of the EMP under the ESRD PPS are set forth below.

Comment: Several commenters were supportive of the proposal to no longer apply the EMP under the ESRD PPS. The commenters agreed with the underlying rationale that the EMP is no longer needed because ESAs have been incorporated into the ESRD PPS. Some of the commenters asked that we confirm that hemoglobin or hematocrit value codes are still required on Medicare claims.

Response: We appreciate the commenters' support. With regard to the reporting of hemoglobin or hematocrit value codes, ESRD facilities are required to continue to report all necessary information for the ESRD Quality Incentive Program under the ESRD PPS, which includes hemoglobin or hematocrit values.

Comment: MedPAC and a software company opposed the proposal. The software company stated that in its efforts to better manage hemoglobin cycling in the ESRD population, the company has found there is an opportunity to further reduce overutilization, cut drug waste, and decrease hospitalizations. The company strongly encouraged CMS to preserve the EMP for this reason.

MedPAC stated that the implementation of the ESRD PPS created incentives for ESRD facilities to furnish services more efficiently. MedPAC stated that under the ESRD PPS, in

which all renal dialysis drugs and biological products are included in the payment bundle, ESRD facilities have been more judicious in providing all drugs, including ESAs. For example, MedPAC stated that between 2010 and 2017, use of all renal dialysis drugs and biological products paid under the ESRD PPS has declined by 12 percent per year. MedPAC noted that the decline in the use of ESRD drugs under the PPS has occurred without any negative effect on clinical outcomes.

MedPAC stated that by contrast, the TDAPA, which is an add-on payment adjustment for nearly all renal dialysis drugs and biological products that FDA approves on or after January 1, 2020, may promote excess provision of renal dialysis drug products (to the extent clinically possible). MedPAC explained that paying according to the number of units administered gives ESRD facilities greater profits from larger doses than smaller doses (as long as Medicare's payment rate exceeds providers' costs). MedPAC expressed concern that in addition to increased and unnecessary spending for beneficiaries and taxpayers, overuse of drugs can have negative clinical consequences. MedPAC stated that because of the incentive for potential overuse of drugs paid under the TDAPA policy, CMS should not discontinue the EMP. MedPAC urged CMS to establish a formal monitoring policy for all renal dialysis drugs and biological products that are paid under the TDAPA to address their potential for overuse.

Response: We appreciate the software company's comment that there may still be an opportunity to further reduce overutilization, cut drug waste, and decrease hospitalizations. According to the ESRD PPS monitoring data[34] that is available to the public on the CMS website, we have found that ESA utilization has declined since the implementation of the ESRD PPS with no sustained negative changes in beneficiary health status. We believe that this finding

[34] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Claims-Based-Monitoring.html

indicates, overall, that patients are not suffering negative health consequences and that the EMP adds a layer of unnecessary burden for ESRD facilities at this time.

With regard to MedPAC's concern that renal dialysis drugs and biological products eligible for the TDAPA may increase unnecessary spending for beneficiaries and taxpayers, in addition to potential negative clinical consequences, we will take these concerns into consideration for future monitoring policies. We believe that with near-real-time claims monitoring we have the ability to closely track ESRD facility behaviors and can take action if we see something concerning.

Final Rule Action: After consideration of public comments, we are finalizing the proposal to no longer apply the EMP under the ESRD PPS effective January 1, 2020. We will issue administrative guidance to provide instructions on the technical changes to the claims processing requirements.

5. CY 2020 ESRD PPS Update

a. CY 2020 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share for ESRD PPS

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). In the CY 2015 ESRD PPS final rule we rebased and revised the ESRDB input price index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

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.

We proposed to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2020 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket update based on IHS Global Inc.’s (IGI) most recently available forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. Using this methodology and the IGI first quarter 2019 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2018), the proposed CY 2020 ESRDB market basket increase factor was 2.1 percent.

Under section 1881(b)(14)(F)(i) of the 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. We finalized the detailed methodology for deriving the MFP projection in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and Reports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf. Using this methodology and the IGI first quarter 2019 forecast, the proposed MFP adjustment for CY 2020 (the 10-year moving average of MFP for the period ending CY 2020) was projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2020 ESRD market basket adjusted for MFP was 1.7 percent. This market basket increase is calculated by starting with the proposed CY 2020 ESRDB market basket percentage increase factor of 2.1 percent and reducing it by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending CY 2020) of 0.4 percent.

The comments and our responses to the comments on the proposed productivity-adjusted market basket annual update and MFP adjustment for CY 2020 are set forth below.

Comment: One commenter expressed appreciation for the proposed increase to the ESRD PPS base rate for CY 2020, but expressed concern that the proposed amount will not fully cover costs associated with providing high-quality care to patients, particularly by small and

independent providers with limited resources offering care in many cases to patients in rural and underserved areas where access challenges may be present.

Response: We appreciate the commenter's concern that the proposed annual update factor may not be sufficient to cover the cost of care for small independent providers or those in rural areas. The annual update factor is intended to account for the overall increase in cost of care at the national level. The patient case-mix payment adjustments and the facility level adjustments, such as the rural adjustment and low-volume payment adjustment account for differences in both patient and facility characteristics. These payment adjustments are provided to address the variation of costs of a particular facility relative to the national standard.

Comment: One LDO reiterated its concerns submitted in response to the CY 2019 ESRD PPS proposed rule (83 FR 56961) related to the ability of ESRD facilities to achieve and maintain high levels of productivity gains. The LDO noted that several factors impact the potential for productivity gains including required staffing level minimums and the unique nature of contracted versus employed labor in the ESRD setting. The commenter stated that the current MFP adjustment is a crude measure that does not reflect circumstances unique to ESRD facilities. The LDO further stated that it seeks to engage with CMS to support developing an ESRD-specific MFP in collaboration with Congress and the Bureau of Labor Statistics (BLS).

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. The statute does not provide the Secretary with the authority to apply a different adjustment. 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 noted previously, any change~~s~~ to the MFP adjustment would require a change to current law.

The March 2019 MedPAC Report to Congress finds, "Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital. Providers have become more efficient in the use of dialysis drugs under the PPS." (http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch6_sec.pdf?sfvrsn=0).

While we understand that the kidney care community is interested in an adjustment more specific to ESRD facilities, we encourage commenters to discuss the feasibility of such measures with the BLS, the agency that produces and publishes industry-level MFP. CMS is unable to estimate MFP for ESRD facilities since the publicly available data for the NAICS 621492 Kidney Dialysis Centers is insufficient to develop an estimate using a similar methodology used to estimate Hospital sector MFP in the November 2006 Health Care Financing Review article, "'Hospital Multifactor Productivity: A Presentation and Analysis of Two Methodologies"'. We would also encourage the kidney care community to make available to CMS any research into alternative methods and data sources that could be used to estimate ESRD-specific MFP. Specifically, we would be interested in any information on how cost report data submitted to CMS could be utilized to better understand the operating conditions facing ESRD facilities.

Based on public comments and in accordance with section 1881(b)(14)(F)(i) of the Act, we are finalizing the CY 2020 update to the ESRD facilities as proposed. Also, as noted in the proposed rule and consistent with CMS general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket update or MFP adjustment), we proposed to use such data to determine the final CY 2020 market basket update and/or MFP

adjustment. Therefore, using the IGI third quarter 2019 forecast of the CY 2016-based ESRDB market basket (with historical data through the second quarter of 2019), the final CY 2020 ESRDB market basket increase factor is projected to be 2.0 percent. The final MFP adjustment for CY 2020 (the 10-year moving average of MFP for the period ending CY 2020) is projected to be 0.3 percent. The final CY 2020 ESRD market basket adjusted for MFP is projected to be 1.7 percent. This market basket increase is calculated by starting with the CY 2020 ESRDB market basket percentage increase factor of 2.0 percent and reducing it by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2020) of 0.3 percent.

For the CY 2020 ESRD payment update, we proposed to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56963). We did not receive any public comments on this proposal and therefore are finalizing the continued use of a 52.3 percent labor-related share.

b. 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) core-based statistical area (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 2020, we updated the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We used 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 2020 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final CY 2020 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 website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see 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). As we discussed in

the CY 2020 ESRD PPS proposed rule (84 FR 38359), beginning in CY 2020, the statewide urban average based on the average of all urban areas within the state also will be applied to the Carson City, Nevada CBSA.

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 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We stated that 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 0.4000 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 permanently maintain the wage index floor of 0.4000, because we believed it was appropriate and provided additional payment support to the lowest wage areas. It also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates.

In the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we finalized an increase to the wage index floor from 0.4000 to 0.5000 for CY 2019 and subsequent years. We explained that we revisited our evaluation of payments to ESRD facilities located in the lowest wage areas to be responsive to stakeholder comments and to ensure payments under the ESRD PPS are appropriate. We provided statistical analyses that supported a higher wage index floor and finalized an increase from 0.4000 to 0.5000 to safeguard access to care in those areas. We further explained that we believe a wage index floor of 0.5000 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. 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.

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. Thus, for CY 2020, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38360), we were made aware of a minor calculation error in the file used to compute the ESRD PPS wage index values for the proposed rule. We posted the corrected wage index values on the ESRD PPS payment page and used the corrected values when computing the ESRD PPS wage index values and payment rates for this final rule.

CMS received several comments on the wage index. The comments and our responses are set forth below.

Comment: One LDO and one national dialysis association stated that CMS noted in the proposed rule that it was made aware of a "minor calculation error" in the file used to compute the ESRD PPS wage index values. The agency has since published a corrected file on the ESRD PPS payment web page.

They expressed concern that CMS has not published information to inform stakeholders about the impact of the updated ESRD wage index values on the ESRD PPS base rate. They stated that they believe a revised wage index budget neutrality factor, based on the revised wage indices, may result in a downward effect on the proposed base rate. As the labor-related share represents such a significant component of facility payment, they noted the importance of transparency and accuracy in proposed rates published by CMS so that providers and other stakeholders can understand the impact of proposed policy changes

and provide input during the regulatory comment period. They recommended that CMS retain the prior year's wage indices to ensure consistency and transparency for stakeholders.

While the national dialysis association stated that it was able to run the complex calculations to determine the likely, corrected base rate and associated reimbursement factors, other stakeholders may not be able to utilize the technical files and available methodological information to re-run calculations and derive a corrected base rate. The association stated that independent analysis indicates that the wage index error published in the CY 2020 ESRD PPS proposed rule understated the wage adjustment amount by 0.84 percent across all calculations. The association stated that in the final rule, CMS should correct this error and simultaneously apply a corresponding, corrected budget neutrality factor that will reduce the proposed base rate by approximately $1 per treatment, resulting in approximately $41 million less for dialysis care in CY 2020 than was indicated in the CY 2020 ESRD PPS proposed rule.

The commenter suggested that if CMS discovers an error in the wage indices after publication of the proposed rule, the agency should provide the public with complete information, including the corrected wage indices, wage index budget neutrality factor, and revised ESRD PPS base rate.

Response: We thank the commenter for its comment that we understated the wage adjustment amount by 0.84 percent across all calculations. We note that the minor calculation error was that the wage and hour data for CBSA 31084 were inadvertently doubled. This caused an error in the national average hourly wage, which factors into the calculation of all wage index values. We have changed the programming logic to correct this error. In addition, we corrected the classification of one provider in North Carolina that

was erroneously identified as being in an urban CBSA. We also standardized our procedures for rounding, to ensure consistency.

We also note that it is not uncommon for the ESRD PPS wage index values to change between the proposed and final rules. In this specific case, the proposed rule correction resulted in a wage index budget neutrality adjustment factor that lowered the base rate, but in the time between the proposed and final rule with updated wage index data, the wage index budget neutrality adjustment factor changed and the ESRD PPS base rate was increased. We make every effort to be fully transparent in our calculations and will continue to do so in the future.

Comment: Several health insurance organizations in Puerto Rico commented on the wage index for Puerto Rico, expressing that the historical downward trending of the ESRD PPS wage index is having a negative impact on the funding of Puerto Rico's dialysis program. The commenters stated that despite the 0.10 increase in 2019, there still remains a disparity gap. Currently, the USVI maintains a 0.70 ESRD wage index. The commenters noted that a movement towards parity funding between the two territories would be a significant step in narrowing the disparity-funding gap.

The commenters asserted that a wage index floor of 0.70 would result in rates that more accurately reflect actual cost per treatment based on costs after Hurricane Maria for the years 2018 and 2019. They believe that the average in-center hemodialysis costs for independent facilities in Puerto Rico is $232.25 per treatment using CMS data from 2017. They asserted that this number is significantly higher than the average FFS payment rate for Puerto Rico and significantly lower than the rates contracted by Medicare Advantage companies for the same service. They noted that in-center hemodialysis represents the

majority of the treatments for Puerto Rico ESRD patients. In future reforms to the ESRD PPS wage index system, they suggested that CMS should use adjusted inpatient facility (Part A) wage index values to reverse the wage index "downward spiral" consistently across all Medicare payment systems. In addition, they stated that CMS should consider basing the ESRD PPS wage index on a new survey of ESRD outpatient facility wage costs. Finally, they recommended that CMS assure that the corresponding adjustment in Medicare Advantage benchmarks for ESRD is made to reflect any adjustments in FFS ESRD payments.

Response: We thank commenters for sharing their concerns regarding Puerto Rico's wage index and their opinion of an existing disparity gap, along with the recommendation of a wage index for Puerto Rico of 0.70 and their concern regarding the Medicare Advantage benchmarks for ESRD. We will take these thoughtful suggestions into consideration when considering future rulemaking.

Final Rule Action: We are finalizing the CY 2020 ESRD PPS wage indices based on the latest hospital wage data as proposed. For CY 2020, the labor-related share to which a facility's wage index is applied is 52.3 percent.

c. Final CY 2020 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 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 included one technical correction.

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 in the following paragraphs) plus the 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 2020, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2018. 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 2020 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2018. We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38361) 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 2020 Update to the Outlier Services MAP Amounts and FDL Amounts

For this final rule, the outlier services MAP amounts and FDL amounts were updated using 2018 claims data. In the CY 2020 ESRD PPS proposed rule (84 FR 38361), we noted that, beginning in CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy (calculated to be $21.15 per treatment). For this final rule, we project that for each dialysis treatment furnished, the average amount attributed to the TDAPA is $21.03.

The impact of the final rule update is shown in Table 2, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2019 with the

updated estimates for this final rule. The estimates for the final CY 2020 outlier policy, which are included in Column II of Table 2, were inflation adjusted to reflect projected 2020 prices for outlier services.

TABLE 2: Outlier Policy: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2019 (based on 2017 data, price inflated to 2019)*		**Column II Final outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)**	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$34.18	$40.18	$30.95	$37.33
Adjustments				
Standardization for outlier services	1.0503	0.9779	1.0655	0.9781
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$35.18	$38.51	$32.32	$35.78
FDL amount that is added to the predicted MAP to determine the outlier threshold	$57.14	$65.11	$41.04	$48.33
Patient-months qualifying for outlier payment	7.2%	8.2%	11.35%	10.38%

*Note that Column I was obtained from Column II of Table 11 from the CY 2019 ESRD PPS final rule (83 FR 56968).

As demonstrated in Table 2, the estimated FDL amount per treatment that determines the CY 2020 outlier threshold amount for adults (Column II; $48.33) is lower than that used for the CY 2019 outlier policy (Column I; $65.11). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $38.51 to $35.78. For pediatric patients, there is a decrease in the FDL amount from $57.14 to

$41.04. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $35.18 to $32.32.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2020 will be 10.38 percent for adult patients and 11.35 percent for pediatric patients, based on the 2018 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 2018 claims, outlier payments represented approximately 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2018 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2020.

We believe the update to the outlier MAP and FDL amounts for CY 2020 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: MedPAC requested that CMS clarify the reference to calcimimetic payments being included in total expenditure amounts in the CY 2020 ESRD PPS proposed rule discussion of updating the outlier services MAP and FDL amounts. MedPAC stated that it is not clear how CMS is using calcimimetic expenditure data to estimate the CY 2020 MAP and FDL amounts. MedPAC noted that CMS has previously said that drugs eligible for the TDAPA (including calcimimetics) are not eligible for outlier payments and that the 1 percent target for outlier payments is based on total ESRD PPS expenditures.

MedPAC stated that given that CMS has said that total ESRD expenditure amounts for 2020 include TDAPA expenditures for calcimimetics, they believe CMS proposed to target 1 percent of total expenditures, including TDAPA expenditures in 2020, when establishing the FDL amount. However, MedPAC noted, the outlier pool has been funded through a 1 percent reduction in the base rate (that was applied in 2011 and has remained in effect in each subsequent year by applying all annual updates to the reduced base rate) and therefore does not account for the TDAPA expenditures for calcimimetics, which are currently an add-on payment adjustment to the base rate. MedPAC stated that CMS has not proposed a budget-neutral method for funding the outlier policy in 2020 that accounts for the additional ESRD expenditures from add-on payment adjustments for calcimimetics under the TDAPA policy. MedPAC suggested that CMS should maintain a budget-neutral outlier policy either by excluding the TDAPA expenditures for calcimimetics from the total

ESRD expenditures so that the 1 percent outlier payment target does not include the TDAPA expenditures (that is, the policy applied to the TDAPA payments for calcimimetics in 2018 and 2019), or by reducing the TDAPA expenditures by 1 percent so that funding for the outlier policy accounts for the TDAPA expenditures for calcimimetics. One national dialysis association expressed support for MedPAC's analysis, but did not support MedPAC's alternative recommendation that CMS consider reducing the TDAPA payments by 1 percent so that funding for the outlier policy accounts for the TDAPA expenditures for calcimimetics.

Several commenters expressed concern that CMS has proposed to include the TDAPA costs for calcimimetics in the outlier calculation, even though the drugs eligible for the TDAPA are not eligible for an outlier payment. A national dialysis stakeholder organization noted that while the statute requires CMS to include as part of the single payment amount for the ESRD PPS a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, it does not provide specifics as to how the outlier pool is determined or paid out. The organization acknowledged CMS's position that the TDAPA is part of the ESRD PPS single payment amount but expressed concerned that the calcimimetics should be included in the outlier pool. The organization noted that the CY 2020 ESRD PPS proposed rule estimated that more than $21 per treatment is removed from the base rate by including these drugs in the outlier calculations; yet, there is no ability to recover the dollars and they are permanently removed from the program. The organizations further commented that Congress established an outlier pool so that ESRD facilities treating extraordinarily costly patient are not

disincentivized from doing so, but interpreting the statute to incorporate an add-on payment adjustment into the outlier calculation is inconsistent with this intent.

Another LDO and a national dialysis association expressed concern with CMS' proposal to include TDAPA spending on calcimimetics in the outlier pool for CY 2020. They stated that they see no justification in the rule for CMS to significantly increase the outlier target for CY 2020 by including calcimimetics when it is not statutorily required to do so and when the outlier target has not been achieved under the ESRD PPS in any year since implementation. The commenters stated that this has a decreasing effect on the base rate while increasing the likelihood that CMS will not actually spend these additional dollars on high cost cases, given that calcimimetics do not even qualify for outlier payments in CY 2020. They further stated that it seems incongruous to include calcimimetics expenditures in the outlier pool, given what they called the separate treatment of calcimimetics outside the base rate under the TDAPA and the fact that, under Medicare regulations, these drugs do not qualify toward the outlier calculation while they are eligible for the TDAPA. They recommended that rather than increasing the amount of funding withheld from providers that they are unlikely to see in outlier payments, CMS should exclude calcimimetics (which are not eligible for outlier payment during the TDAPA) from the target percentage for CY 2020.

One national dialysis association opposed CMS' methodology described in the proposed rule to include the TDAPA expenditures for calcimimetics in the calculation for the outlier pool, noting that CMS proposed to add more than $21 per treatment to the ESRD PPS base rate and then withhold 1 percent of this for the outlier pool. They stated this will result in CMS withholding an even greater amount of dollars from the ESRD PPS that,

based on the long history of poor performance in the outlier pool, will not be repaid to facilities. The association stated that CMS's proposal is particularly concerning because drugs paid through the TDAPA (including calcimimetics) and devices paid through the proposed TPNIES are not eligible for the outlier pool. Therefore, the association stated, any increase in the withhold for the outlier pool as a result of the TDAPA and the proposed TPNIES will have no correlation to utilization of the outlier pool. The association objected to CMS increasing the withhold for the outlier pool knowing that the withheld dollars will not be returned to the system for patient care.

The association does not believe that CMS should finalize the proposed outlier methodologies that would include expenditures for the TDAPA or the proposed TPNIES in the outlier calculation. The association stated that CMS has sufficient statutory authority to exclude both the TDAPA and the proposed TPNIES from the outlier pool calculation and should do so in the final rule for CY 2020 and beyond. The association noted that there is no statutory requirement that the outlier pool include the ESRD PPS base rate plus the TDAPA or TPNIES. Nor does the ESRD PPS statute require the outlier pool to be based on the total payments made under the ESRD PPS.

Response: We recognize the confusion by the commenters regarding our discussion of calcimimetics and the outlier policy, and we would like to clarify we did not propose any changes to the outlier policy methodology in the CY 2020 ESRD PPS proposed rule, nor did we make any changes to the methodology when calculating the FDL amounts published in the CY 2020 ESRD PPS proposed rule. The projected total ESRD PPS outlier payment for CY 2020 is 1 percent of the sum of ESRD PPS base rate expenditures and TDAPA expenditures. We acknowledge that including the TDAPA expenditures in this calculation

results in a larger than expected outlier payment compared to a scenario in which these TDAPA expenditures are not included. However, the TDAPA is a part of the ESRD PPS, and expenditures for the TDAPA are ESRD PPS expenditures. Because of this, these amounts are used when updating the outlier thresholds. We also note that other renal dialysis items and services, such as composite rate items and services, are not eligible outlier services but their expenditures are included in the overall ESRD PPS expenditures and are therefore taken into account when calculating the FDL amounts. We will take these concerns into consideration for future rulemaking.

Comment: An LDO expressed concern about extending outlier payment eligibility subsequent to applying a TDAPA or TPNIES as the sole payment mechanism for new treatments. They noted that CMS has recognized that outlier payments address "unusual variations in the type or amount of medically necessary care" related to patient conditions such as frailty, obesity, and comorbidities, such as cancer. The LDO asserted that using the outlier pool in this manner goes beyond its intent and design, and will always lead to lower reimbursement relative to the TDAPA and TPINES. The LDO stated that there is no guarantee that a facility would receive any payment for the new treatment. The LDO suggested that an ESRD facility would at best receive the equivalent of ASP-20 percent less the sequestration's impact for a drug or biological product. The LDO stated that any relief under this policy would likely be further compromised by the lack of outlier payment pool parity.

Some commenters also suggested that CMS adjust the outlier percentage to more accurately represent the percentage of total payments that have been historically paid under the outlier policy or otherwise address what appears to be weakness in CMS' approach.

Finally, they recommended that CMS establish a mechanism in the ESRD PPS to return unpaid amounts withheld from providers as part of the target percentage when it does not achieve the 1 percent outlier policy in a given year.

Response: We appreciate the commenters' concerns regarding the incorporation of TDAPA or TPNIES products into the outlier policy after the respective add-on payment adjustments end. As we have stated in the TDAPA and TPNIES sections above, these add-on payment adjustment are to support the ESRD facilities in the uptake of new and innovative drugs and biological products and equipment and supplies. We believe that once these products complete the TDAPA or TPNIES period that they compete in the outlier space. However, we note that the TEP will address the outlier policy as part of its efforts to refine the ESRD PPS. In addition, we will take these concerns into consideration for future rulemaking.

Comment: A physician association commented on the proposed pediatric adjustment for outlier payments of 8.2 percent. The association noted that the pediatric outlier amount is decreasing as a result of a decrease in utilization of these services in the pediatric population. The association expressed concern that the outlier calculation does not currently capture all of the services pediatric ESRD patients require, including management of co-morbidities seen in many pediatric dialysis patients such as failure to thrive and seizure disorder. Additional unique costs are for care coordination, as the pediatric dialysis unit frequently functions as the child's medical home. The association stated that CMS should ensure that the pediatric outlier policy recognizes conditions and services unique to the pediatric population, and requested that CMS examine the accuracy of its data in capturing pediatric co-morbidities before implementing any cuts to the pediatric outlier services. The

association also noted that any pediatric modifiers should be based on actual cost data from pediatric dialysis facilities for recent years. Without adjustments based on accurate cost data, the association maintained, the long-term economic viability of pediatric dialysis units will be jeopardized, and adult units will be further disincentivized to meet the special needs of their pediatric patients who are unable to access specialized pediatric dialysis units.

Response: We note that outlier payments are based on services billed on claims. As a result, the pediatric thresholds are based upon reported data. In addition, the reduction to the FDL amount reflects that outlier payments did not reach the 1 percent target percentage. When that occurs, the FDL amount is lowered so that more claims qualify for outlier payment so that 1 percent of total ESRD PPS payments are outlier payments. In response to the physician association's suggestion that we capture all of the services pediatric ESRD patients require, including management of comorbidities seen in many pediatric dialysis patients such as failure to thrive and seizure disorder, we intend to address data issues through the next TEP meeting which will inform the next refinement of the ESRD PPS.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2020 displayed in Column II of Table 2 of this final rule and based on CY 2018 data.

d. Final Impacts to the CY 2020 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, the 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 the TDAPA (as finalized in section II.B.1.e of this final rule). Beginning in CY 2020 the per-treatment payment amount also will be adjusted for any applicable TPNIES (as finalized in section II.B.3.b.iii of this final rule).

ii. Annual Payment Rate Update for CY 2020

The ESRD PPS base rate for CY 2020 is $239.33. 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 2020 projection for the final ESRDB market basket is 2.0 percent. In CY 2020, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously, the final MFP

adjustment for CY 2020 is 0.3 percent, thus yielding a final update to the base rate of 1.7 percent for CY 2020. Therefore, the ESRD PPS base rate for CY 2020 before application of the wage index budget-neutrality adjustment factor would be $239.27 ($235.27 x 1.017 = $239.27).

- 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 2020, 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). We computed the final CY 2020 wage index budget-neutrality adjustment factor using treatment counts from the 2018 claims and facility-specific CY 2019 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2019. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2020. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2020. The total of these payments became the new CY 2020 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2020 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2020 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates.

The final CY 2020 wage index budget-neutrality adjustment factor is 1.000244, based on the updated wage index data. This application would yield a final CY 2020 ESRD PPS base rate of $239.33 ($239.27 × 1.000244 = $239.33).

The comments and our responses to the comments on our proposals to update the ESRD PPS base rate for CY 2020 are set forth below.

Comment: A professional association expressed appreciation for the proposed increase to the ESRD PPS base rate for CY 2020, but noted that the proposed amount will not fully cover costs associated with providing high-quality care to patients, particularly by small and independent providers with limited resources offering care in many cases to patients in rural and underserved areas where access challenges may be present. The commenter stated that the proposed payment increase will not sufficiently cover the annual growth in costs for ESRD facilities necessary to offer high-quality care to pediatric and adult ESRD patients. Particularly with respect to the provision of home dialysis, the association underscored that only 2 vendors currently offer home dialysis equipment and supplies. They further stated that the home dialysis equipment and supplies have increased in cost by 20 percent to 30 percent. The commenter asserted that the ESRD PPS does not reflect these significant cost increases in home dialysis equipment and supplies. The association noted that MedPAC reported an overall -1.1 percent Medicare margin for ESRD facilities in its 2019 March Report to Congress, including a -5.5 percent margin for rural facilities and a -21.3 percent margin for facilities in the lowest quintile by volume.

Response: We appreciate these comments. 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 ESRD PPS 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 2020 ESRD PPS base rate is appropriate despite the challenges some ESRD facilities experience. We also continue to believe that the payment adjustments help mitigate the challenges faced by those facilities that are eligible for the adjustments. We note that the ESRDB market basket for CYs 2015 through 2018 was reduced in accordance with section 217(b)(2) of PAMA but for CY 2019 and CY 2020, ESRD facilities are getting the full productivity-adjusted ESRDB market basket update, which results in increased per treatment payments.

Final Rule Action: We are finalizing a CY 2020 ESRD PPS base rate of $239.33.

C. Miscellaneous Comments

We received many comments from beneficiaries, physicians, professional organizations, renal organizations, and manufacturers related to issues that were not the subject of proposals and therefore, were out of scope of the CY 2020 ESRD PPS proposed rule. These comments and our responses are summarized below:

Comment: MedPAC noted that PAMA required that the Secretary conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services, consistent with a prior MedPAC

recommendation. MedPAC noted that in September 2015, CMS awarded a contract to conduct the audit. MedPAC requested that CMS release the final results of the audit.

MedPAC noted that in the CY 2019 ESRD PPS final rule, CMS said that the audit process is complete and the audit staff are reviewing the findings. MedPAC emphasized the importance of auditing the cost reports that ESRD facilities submit to CMS to ensure that the data are accurate. 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. MedPAC noted that 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 that Medicare does not allow.

Response: We appreciate MedPAC's thoughts and suggestions on our cost reports and audits. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56973), the audit process is complete. CMS is conducting follow-up activities related to the audit to obtain summary results and investigating what adjustments were made on the cost reports of specific ESRD facilities. We will discuss the results when these follow-up activities are available in a future rule.

Comment: A professional association suggested that CMS implement changes to Medicare cost reports, claims, and Explanation of Benefits (EOB) forms to allow for

separate identification, coding, and reimbursement of the TDAPA-eligible products so that providers and CMS can more easily track use of and spending on these therapies. The professional association stated that currently, many facilities do not have a clear understanding of how much reimbursement they receive specifically for each calcimimetic claim because the Medicare EOBs do not separate out calcimimetic reimbursement. To remedy this, the professional association recommended that Medicare EOBs should reflect separately all procedures, pharmaceutical products, laboratory tests, etc. so that these items are able to receive separate reimbursement and able to be appropriately tracked and reported on CMS Provider Statistical & Reimbursement Reports and facility cost reports.

Responses: We appreciate the commenter's suggestion for transparency of payment directly related to the TDAPA. While this add-on payment adjustment is one component of the ESRD PPS payment amount as described in the newly revised § 413.230, in Change Request 10065,[35] we included instruction for the contractors to capture the payment amount directly related to the TDAPA and make this information available in reports. Therefore the CMS Provider Statistical & Reimbursement Report is capturing this value.

Comments: Several commenters suggested refinements to the ESRD PPS with regard to the case-mix adjusters. A patient advocacy organization requested that CMS ensure the patient case mix adjusters are serving their intended purpose. The organization is concerned that using cost reports as the data source for the age, weight, BSA, and BMI case mix adjusters are neither reliable nor reflecting the patient characteristics that clinicians believe are drivers of higher costs. The organization stated that it agrees with MedPAC and supports the elimination of the co-morbid case-mix adjusters for pericarditis, gastrointestinal tract bleeding with hemorrhage,

35 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018-Transmittals-Items/R1999OTN.html?DLPage=1&DLEntries=10&DLFilter=10065&DLSort=1&DLSortDir=ascending.

hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome. The organization noted that the documentation of these conditions can be burdensome, and it has found limited benefit to the use of information collected. The organization stated that misaligned payment adjusters can negatively impact a facility's ability to provide individualized high-quality care to pediatric and adult ESRD patients, and this is concerning, as it creates greater financial risk for ESRD facilities, particularly for small and independent facilities with limited resources, that are bearing financially burdensome costs for costly patients. The organization stated that returning the funding to the ESRD PPS base rate will benefit patient care. The organization urged CMS to eliminate comorbidity adjustments from the payment system until the agency develops appropriate adjusters that accurately capture variance in costs of care for particularly high-cost, high-acuity patients, and work quickly with clinicians to revise the patient adjusters to ensure they serve their purpose of accounting for higher cost patients.

An LDO commented on the shortcomings of the case-mix adjusters. The LDO provided a detailed analysis of internal treatment run time data, showing that costs comprising nearly 40 percent of the market basket rate, wages, salaries, and benefits, had virtually no correlation to age. The LDO stated that it focused on these costs because there is no patient-level variation in housekeeping and operations, administration, and capital expenses, and thus no age correlation. Although costs for pharmaceuticals and laboratory services do vary minimally by patient, their correlation to age is ambiguous due to confounding with the BSA, BMI, and outlier adjustments. Given the consistency in treatment run times across age groups, the LDO noted that it was difficult to understand the nearly 15 percent swing in relative costs between patients aged 45 to 59 and patients aged 70 to 79 under the 2011 and 2016 models. The LDO further noted that it, along with other members of the kidney care community, and MedPAC have consistently raised

concerns about the use of facility cost report data in developing patient-level adjusters. The LDO stated that the mean treatment run time analysis may not be achieving the intended purpose.

A professional association noted that during the December 8, 2018 ESRD PPS Technical Expert Panel (TEP) meeting convened by CMS, the panelists shared the same concerns as the LDO about alignment of resource use with payment with regard to patient-level adjusters.. The association stated that even when pressed to try to identify additional new adjusters, the vast majority indicated that very few adjusters are truly necessary for the ESRD population.

Some commenters noted concern with the low-volume and rural adjustments, and referenced MedPAC's concern about the overlapping nature of the low-volume and rural adjusters in its most recent Commission meetings. Commenters described MedPAC's April 2019 meeting, in which the staff presented an example of a single low-volume and isolated (LVI) facility adjuster that would better target payments. Some professional associations stated that they conceptually support such an approach. The structure of the low-volume payment adjustment (LVPA) and rural payment adjuster resulted in more than 50 percent of ESRD facilities that received the LVPA also claiming the rural adjuster. Commenters noted that MedPAC's analysis to date supports a conclusion that these adjusters have not led to an efficient distribution of resources or had much impact in improving a low-volume or rural ESRD facility's financial position. An LDO said CMS should explore modifying the low-volume and rural adjusters, such as creating a 2-tiered low- volume adjuster as MedPAC has discussed, and by considering a rural ESRD facility's coverage mix. One healthcare provider urged CMS to consider additional ways to appropriately reimburse low volume, rural facilities. The healthcare

provider noted CMS should be aware of several closures of small rural facilities in the Midwest and stated that these closures are directly related to operational losses sustained by the ESRD facilities over a period of several years. The healthcare provider urged CMS to evaluate the base rate and rural and low volume adjusters to ensure ESRD facilities are reimbursed at a rate that covers the cost of care in rural communities. The healthcare provider stated that appropriate reimbursement rates will allow facilities to maintain high quality care and maintain local access to dialysis services.

A national dialysis stakeholder organization commented on the overall underfunding of ESRD facilities due to patient-level, facility level, add-on payment and outlier adjustments. The organization asserted that the application of these current policies results in the actual dollars CMS pays out for ESRD care to be significantly less than what the Congress had indicated it should be. The organization stated that while sequestration continues to be a driving source of underpayments, the underpayment amount attributable to other factors, which are due to a mismatch among adjusters frequencies assumed by the standardization factor compared to actual payment increased substantially in 2018, remains high. The organization noted that estimations indicate that, taken together, the total underpayment for the PPS per treatment in 2018 was $11.11. The organization further stated that the underpayment due to the outlier pool was $1.54 per treatment. Sequestration accounted for $4.45 per treatment, with the ESRD QIP taking out 25 cents per treatment. The organization stated that the remainder of the underpayment appears to be due to the fact that CMS has incorporated the expenditures for calcimimetics into the outlier pool calculation. The commenter strongly objected to this inclusion. The commenter stated that given the negative margins, each dollar that comes out of the program reduced the funding available to support patient care and innovation.

Response: We appreciate the concerns raised by stakeholders regarding the technical nature of the ESRD PPS model. We intend to address these issues through the next TEP meeting which will inform the next refinement of the ESRD PPS. We will also consider these concerns for future rulemaking.

Comment: An LDO expressed appreciation for CMS' response to comments on the CY 2019 ESRD PPS proposed rule regarding the challenges ESRD facilities encounter when trying to obtain information on a patient's comorbid conditions. The LDO agreed that this information is important in developing comprehensive, effective treatment plans. The LDO also agreed that collecting these data should not be burdensome or cumbersome for ESRD facilities, but stated that it is finding it particularly difficult to get these data when a patient overwhelmed by a health crisis that requires a hospitalization forgets to provide necessary contact information. In these situations, despite several attempts, the LDO states that it frequently cannot obtain discharge instructions/summaries, pending laboratory results, and other relevant information on its patients' behalf. The LDO noted that this lack of communication complicates dialysis providers' ability to submit documentation necessary to receive comorbidity adjustments, which when left unclaimed lead to inappropriate reductions in ESRD PPS payments. The LDO disagreed with CMS's suggestion that in the absence of data necessary to receive a comorbidity adjustment, receiving funds through the outlier pool is an acceptable alternative.

The LDO suggested that, rather than a work-around through the outlier policy, CMS should take steps to ensure that the comorbidity adjusters perform as intended. The LDO stated that without an explicit requirement to do so, some providers rarely, if ever, make the necessary information available to ESRD facilities. The LDO recommended that 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.

Response: We appreciate the LDO's concerns regarding the difficulties of obtaining documentation. We note that the agency has addressed this concern in the final rule entitled, "Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care" (84 FR 51836).[36]

Comments: Two commenters noted that unrecovered bad debt cuts into reimbursement. One professional association suggested that we make the TDAPA-eligible products eligible for bad debt reimbursement. The commenter stated that the TDAPA-eligible products are expensive for both the ESRD facilities that administer them and the Medicare beneficiaries who pay 20 percent co-insurance with their use. Small and independent facilities with limited resources face especially significant challenges in providing the TDAPA-eligible products to patients when they risk not receiving full payment, inclusive of beneficiary cost-sharing, for the costs associated with acquiring, storing, and administering these therapies. The association emphasized that all ESRD Medicare beneficiaries should have access to the medications they need to treat their ESRD-related medical conditions to improve or maintain their health and prevent hospitalizations or other costly therapies and interventions without concern for their affordability.

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36 https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals.

Several commenters provided suggestions on the incorporation of calcimimetics into the ESRD PPS base rate. Commenters urged CMS to work with stakeholders when developing a mechanism that does not result in facilities that provide the drugs used by only a small percentage of dialysis patients do so at a significant loss, while facilities that do not provide these drugs receive additional payments because the amount added to the base rate is distributed evenly across all payments. Commenters requested that before CMS incorporates costs for these drugs into the ESRD PPS base rate, it consider how their limited utilization will impact the distribution of dollars that will be added.

One drug manufacturer suggested that CMS should have the option to lengthen the duration of the TDAPA payment period for new renal dialysis drugs and biological products in existing ESRD PPS functional categories beyond 2 years, and use the language "at least 2 years" for these products similar to the language for products in new ESRD PPS functional categories. An LDO and a national dialysis association commented that CMS should ensure accurate expense accounting by including the ESRD network fee on cost reports. The association noted that the composite rate has been replaced by the ESRD PPS, but the 50 cents reduction has remained intact. The commenters noted that when Congress first created the ESRD Networks in 1978, the programs were funded through the appropriations process, with the goal of establishing funding for the programs through a network fee that reduced payments to dialysis facilities was to ensure stable funding for these programs. They noted that the history is silent as to whether this ESRD network fee should be accounted for on the ESRD cost reports. The association recommended CMS account for the ESRD network fee as a "revenue reduction" on the Cost Report. This addition could influence policymakers to increase the payment rate over time, better aligning cost reporting with the basis of payment.

However, they do not think adding this information will affect the payment rate directly. They noted that since Medicare based rates on total historic payments, then use of actual historic payments means the reduction has already been included in its data. The association maintained that the cost reports (1) have not been used in calculating payment rates in a way that would affect the payment rates, and (2) have been used in the regression analysis to estimate adjuster values, but this change should not affect these analyses as the revenue reductions do not vary with any patient, facility or modality characteristic.

A dialysis organization encouraged CMS to include the $0.50 ESRD network fee in dialysis facilities' cost reports, noting that the fee's exclusion understated facilities' costs by more than $20 million in 2017. The organization asserted that since neither the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), which established the network fee, nor accompanying House report address the fee's inclusion or exclusion, CMS has the necessary authority to implement this policy change, and the organization encouraged CMS to explore other policy guidance avenues to add the network fee as a revenue reduction on Worksheet D effective with CY 2020 ESRD facility cost reports.

Two LDOs and a national dialysis organization requested CMS change its TDAPA billing guidance for ESRD facilities to report oral drugs on a claim from the amount consumed (or amount according to the plan of care) to the amount dispensed. The LDO stated that documenting the amount consumed is overly burdensome and creates a significant challenge to dialysis providers, and ultimately cannot be proven for medications taken by patients at home.

The commenters noted that this creates a significant challenge for ESRD facilities. Over the course of a treatment, a lower or higher dose than initially recommended may be

needed due to changes in a patient's condition. Other practical matters, such as a patient's relocation that necessitates the delivery of services at a different, geographically closer facility, make the requirement even more complicated and impractical. The commenters noted that the policy leads to losses for facilities that are not incurred by other provider types or Part D pharmacies and also makes facilities unfairly financially responsible for the entire amount dispensed. For oral drugs delivered through the ESRD PPS, the commenters stated, there is a disconnect between oral drugs prescribed for daily use, including days that do not include a dialysis treatment, and the "per treatment" payment methodology. This disconnect can result in ESRD facilities being unable to report oral drug utilization on days without a dialysis treatment. The commenters noted that current CMS policies require providers to attest in good faith on claims the amount of certain oral drugs consumed by beneficiaries, but this is not possible for dialysis providers, who cannot track beneficiary conduct in their homes on non-treatment days. The commenters therefore urged CMS to allow the reporting of the amount of dispensed but not consumed by beneficiaries as a more accurate and fair representation of what is under the control of the facility.

The commenters stated that this change would align the reporting requirement with those applied to other sectors including a skilled nursing facility (SNF) providing immunosuppressants and a hospital outpatient department providing patients with more than a 1-day supply of an anti-cancer drug. The commenters maintained that this modification also would ensure that CMS remains neutral with respect to providers' prescribing decisions and that patients have good access to the formulation that best meets their clinical needs. They also suggested that CMS provide guidance and appropriate reimbursement for a pharmaceutical product that must be discarded due to patient death, prescription change,

facility transfer, hospitalization, transplantation or other circumstances that are outside the control of the ESRD facility. The commenters suggested that CMS provide guidance for product that, despite best efforts, has been lost in delivery, or misplaced by the beneficiary, and allow the facility to submit, and be reimbursed for, the second supply, perhaps through use of a modifier or similar system.

One national dialysis stakeholder organization and 1 drug manufacturer urged CMS in the coming year to work with the industry to find a better price proxy for non-ESAs that are not over the counter (OTC) vitamins. Specifically, they recommended that CMS use the BLS Series ID: WPS063 Series Title: PPI Commodity data for Chemicals and allied products-Drugs and pharmaceuticals, seasonally adjusted. They noted that the current category references "vitamins," in a way that does not appropriately capture the price of drugs that fall within this category. Currently, the drugs in this category represent a small portion of the overall cost of providing dialysis services; however, the need for a more accurate and appropriate price proxy for oral and non-ESA drugs should be addressed now. Vitamin D analogs in this category, such as doxercalciferol and paricalcitol, are synthesized hormones that suppress PTH without inducing severe hypercalcemia, distinguishing them from OTC vitamins. They stated that these products are all unique chemical entities, FDA-approved, available by prescription only, and indicated for the treatment of secondary hyperparathyroidism (SHPT) which contributes to the development of bone disease. Moreover, these prescription drugs are classified by the U.S. Pharmacopeia in the Medicare Model Guidelines, a classification system that supports drug formulary development by Medicare Part D prescription drug plans, as "Metabolic Bone Disease Agents," not vitamins.

The commenters stated that the creation of the TDAPA for new renal dialysis drugs

and biological products will likely result in a shift in drug mix within the bundle, as well as introduce new oral products that deserve an accurate price proxy for updating. They noted that there are new drugs in the pipeline currently that, if the ESRD PPS does not create disincentives for their continued development, will likely be added to the ESRD PPS bundled payment during the next 2 to 3 years. The association recommended that CMS establish an alternative price proxy for these other drugs that is based on prescription drugs rather than vitamins and that would include fewer OTC drugs.

A drug manufacturer asked CMS to clarify how it will evaluate new products to determine whether they will fall within the definition of a "renal dialysis service."

An LDO commented that the absence of adequate and sustained payments in the ESRD PPS bundled payment for new treatments will not just affect ESRD beneficiaries in Medicare FFS, but will also flow into, and lower, Medicare Advantage (MA) ESRD payments. The LDO urged CMS to consider this impact and how it will affect ESRD beneficiaries, who will have the opportunity starting in 2021 to enroll in an MA plan just like other beneficiaries.

A physician association stated that it continued to have significant concerns about the pediatric case mix adjuster and the undervaluation of pediatric ESRD supplies and services. The association noted that it has previously requested that CMS evaluate pediatric facility Medicare cost reports and ensure that the Medicare claims forms and CROWNWeb data accurately reflect what is required to deliver quality care to pediatric patients. The association stated that the data CMS is using fail to reflect the necessary resources and associated costs of delivering pediatric ESRD care. In particular, the association stated that there is not a good mechanism to report some of the costs uniquely associated with pediatric patients, such as costs associated with the allied health team. The association recommended that CMS look beyond the currently required

report data and consider what expenses unique to pediatric dialysis should be included to appropriately reflect the costs of pediatric ESRD care, and to improve the completeness and accuracy of pediatric data being reported.

The association listed certain unique expenses related to pediatric dialysis care that should be reflected in any pediatric ESRD facility payment formula, including: (1) increased reliance on registered nurses to provide dialysis care; (2) developmental/behavioral specialists; (3) more frequent assessment by pediatric dieticians; (4) social workers, teachers, and designated liaisons to interface regularly with schools; and, (5) a broad array of dialysis supplies.

The commenter noted that without accurate reimbursement to pediatric facilities, those who are specially trained to care for this unique patient population, as well as pediatric ESRD patients themselves, face an uncertain future. The commenter stated there is already a shortage of pediatric nephrologists and inadequate reimbursement will further exacerbate this shortage and result in limited access of pediatric dialysis patients to specialized facilities with pediatric personnel trained to care for their unique needs. The commenter noted that the result will likely be worse health outcomes for children with ESRD, with the potential for higher costs of care when these children mature to adulthood. The commenter stated that the ultimate goal should be to ensure that reimbursement is appropriate so that pediatric facilities and providers can continue to provide high quality services to those in need.

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 2020 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule. We will consider these comments and issues when developing ESRD PPS policies in the future.

III. CY 2020 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 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 an ESRD facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

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

adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2020 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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 38330 through 38421), hereinafter referred to as the "CY 2020 ESRD PPS proposed rule," was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that proposed rule, we proposed to update the AKI dialysis payment rate. We received approximately 4 public comments on our proposal, including comments from ESRD facilities; national renal groups, transplant organizations; 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 2020 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2020

1. CY 2020 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.5.d of the CY 2020 ESRD PPS proposed rule (84 FR 38362), the CY 2020 proposed ESRD PPS base rate was $240.27, which reflected the proposed market basket, multifactor productivity adjustment, and CY 2020 wage index budget-neutrality adjustment factor. Therefore, we proposed a CY 2020 per treatment payment rate of $240.27 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.5.b of the CY 2020 ESRD PPS proposed rule (84 FR 38359 through 38360). 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 2020 AKI dialysis payment rate of $240.27, adjusted by the ESRD facility's wage index.

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

Comment: Some commenters noted that they support the proposed AKI payment rate for CY 2020. They noted that in the CY 2017 ESRD PPS final rule, CMS announced that it would be developing a formal monitoring program for AKI dialysis payments, but the specifics have yet to be published. They said they would also find it helpful to understand how CMS is monitoring the AKI benefit. They stated their support for CMS's plan to develop a program to monitor utilization of dialysis and all separately billable items and services furnished to beneficiaries with AKI. They reiterated their interest in maintaining a dialogue as part of this monitoring program to ensure that the payments for AKI patients are adequate and stated that it may be necessary for CMS to establish an "AKI adjustment" to the payment rate to address the differences in the services provided to AKI patients from those provided to ESRD patients. They encouraged CMS to make the AKI benefit's monitoring plan and any insight obtained to date available to stakeholders, noting that transparency regarding this information is crucial to supporting our shared objectives of ensuring AKI payment adequacy.

Response: We thank the commenters for their support of the AKI payment rate. We are in the process of evaluating the methodology to be used for determining significant differences in resource use with AKI patients in contrast to ESRD patients. We have met with dialysis center physicians affiliated with academic medical centers to discuss differences in care requirements for the AKI patient and the ESRD patient. The stated that they separate their AKI patients from their ESRD patients and monitor their treatment, recovery, or progression to ESRD. Along with our in-house medical officers, our data contractor employs 2 nephrologists with whom we are consulting on differences in treatment of AKI patients and ESRD patients in order to evaluate

resource use and a potential AKI adjustment. Such resource use would include time on dialysis machine, frequency of dialysis, drug requirements and lab tests, treatment protocols and additional practitioner time to evaluate medical status. In addition, CMS has an ESRD monitoring and evaluation team in the Centers for Clinical Standards and Quality clinical monitoring, that regularly discusses the monitoring of ESRD beneficiaries. We continue to be interested in feedback and data from the public regarding AKI patients and we intend to continue researching these issues and potentially addressing them through rulemaking and other mechanisms in the future.

Comment: One nursing association emphasized the critical role of nephrology nurses and the increased responsibilities that are placed on them when managing the complex nursing and care needs of patients with AKI. The association stated that the unique and distinct characteristics of the ESRD and AKI patient populations require critical differences in treatment protocols. The association noted that AKI patients require more vigilant monitoring, particularly in infection prevention, blood pressure management, more frequent laboratory testing, additional medication administration, and increased educational needs. The care of an AKI patient often requires more care coordination of the interdisciplinary team. The association stated that these are not patient care responsibilities that can be delegated to technicians or other staff; only specialized nephrology nurses can provide the type of highly intensive and coordinated care that is necessary for these patients to achieve improved health outcomes. Given the increased nursing time required to provide high-quality care to AKI patients, the commenter urged CMS to recognize the specialized high-quality nursing care that nephrology nurses offer as CMS considers modifications to the AKI payment policy.

Response: We thank the commenter for noting the differences such as increased

monitoring of signs for infection, infection prevention, blood pressure management, more frequent laboratory testing and increased nursing time in the AKI patients. As we noted previously, we are aware of these differences and would encourage the association to continue to share information with us as we evaluate the differences in resource use of the ESRD and AKI patient. We will take all the cited examples into consideration for AKI monitoring and for future rulemaking.

Comment: One commenter suggested that AKI payments be competitive with ESRD PPS payments. The commenter noted that transplant recipients often have AKI early after transplant surgery and require dialysis support until transplant function is established. The commenter stated that currently, outpatient dialysis centers can receive payment for patients that are dialyzed for the diagnosis of AKI, however, most centers are not dialyzing these patients. The commenter stated that it suspects this is because the ESRD facilities do not want to give up a chronic spot to an acute patient that may only require treatment for a limited time. The commenter stated that the chronic ESRD patient is a guaranteed bundled payment patient. Physicians typically see the AKI patient weekly for 4 weeks. The commenter stated that if a patient is only in the unit 1 week as an acute patient, the reimbursement is much less and therefore, the units tend to not want these patients in the chronic chairs.

Response: We thank the commenter for sharing this insight into the post-transplant scenario when it involves AKI patients. 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.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI

payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2020 ESRD PPS base rate is $239.33. Accordingly, we are finalizing a CY 2020 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as $239.33.

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

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules: 75 FR 49030, 76 FR 628, 76 FR 70228, 77 FR 67450, 78 FR 72156, 79 FR 66120, 80 FR 68968, 81 FR 77834, 82 FR 50738, and 83FR 56922. We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Finalized Policies for the ESRD 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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 38330 through 38421), hereinafter referred to as the "CY 2020 ESRD PPS proposed rule," was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that rule, for the ESRD QIP, we proposed updates to the ESRD QIP, including for PY 2022

and PY 2023. We received approximately 29 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.

The comments and our responses to the comments on the ESRD QIP are set forth below.

Comment: Commenters provided feedback on adding new measures to the ESRD QIP. Commenters' suggestions for new measures included NQF-endorsed measures of dialysis adequacy, different Kt/V measures for different dialysis patient demographics, an NQF-endorsed alternative to the ESRD QIP's Ultrafiltration reporting measure, and a depression measure specific to the ESRD community.

Response: We thank the commenters for their recommendations and welcome feedback on ways to improve the program, including the adoption of new or revised measures. However, we note that these comments are not responsive to a proposal included in the CY 2020 ESRD PPS proposed rule, and therefore, are considered beyond the scope of the CY 2020 ESRD PPS proposed rule. We refer readers to the CY 2019 ESRD PPS final rule (83 FR 56982 through 57016), 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) for discussions of the measures that we have previously adopted for the ESRD QIP.

C. Updates to Regulation Text

We proposed to revise the requirements at § 413.178 by redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively. In addition, we proposed to add a new

paragraph (d) to specify the data submission requirements for calculating measure scores. Specifically, we proposed to codify the requirement that facilities must submit measure data to CMS on all measures. We stated that this proposed regulation text would codify previously finalized policies and would make it easier for the public to locate and understand the Program's quality data submission requirements.

Additionally, we stated that the proposed text in new paragraph (d)(2) would codify our proposed policy (discussed more fully in section IV.E.2 of this final rule) to adopt the performance period and baseline period for each payment year automatically by advancing 1 year from the previous payment year. At § 413.178(d)(3) through (d)(7), we proposed to codify requirements for the Extraordinary Circumstances Exception (ECE) process, including a new option for facilities to reject an extraordinary circumstance exception granted by CMS under certain circumstances. We stated that this new option would provide facilities with flexibility under the ECE process. We also proposed this provision to provide clear guidance to the public on the scope of our ECE process. We invited public comments on these proposals.

The comments and our responses regarding the proposed regulation text are set forth below.

Comment: Commenter expressed support for the proposal to codify the requirement that facilities must submit measure data to CMS on all measures. Commenter noted its appreciation of the predictability that will result from CMS codifying its previously finalized policies.

Response: We appreciate and thank the commenter for its support.

Comment: Commenters expressed support for CMS's proposal to codify its requirements for the ECE process, including a new option for facilities to reject an ECE granted by CMS under certain circumstances.

Response: We appreciate and thank the commenters for their support.

Final Rule Action: After consideration of the public comments we received, we are finalizing our proposed regulation text with one technical change. Section 413.178(d)(5) now clarifies that CMS will not consider an ECE request unless the facility making the request has complied with the requirements in § 413.178(d)(4).

D. Requirements Beginning with the PY 2022 ESRD QIP

The PY 2022 ESRD QIP measure set includes 14 measures, which are described in Table 3. For more information on these measures, including the two measures that are new beginning with PY 2022 (the Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure and the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure), please see the CY 2019 ESRD QIP final rule (83 FR 57003 through 57010).

TABLE 3: PY 2022 ESRD QIP Measure Set

NQF #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
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.
2979	Standardized Transfusion Ratio (STrR), a reporting measure37 Risk-adjusted STrR for all adult Medicare dialysis patients. Ratio of the 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
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. 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.
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.
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.

[37] We are finalizing in section IV.D.2.b of this final rule that beginning with the PY 2022 ESRD QIP, the STrR measure will be scored as a reporting measure.

NQF #	Measure Title and Description
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.
1463*	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
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.
N/A	Ultrafiltration Rate, a reporting measure Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
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.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to CDC.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performance and documented by an eligible professional

The comments and our response to the comments regarding our continuing measures are set forth below.

Comment: Commenters provided feedback on various aspects of measures that are continuing in PY 2022. These comments included recommendations to keep or remove continuing measures from the Program, recommendations to modify continuing measures (for example, by revising the Kt/V clinical measure's pooled approach in combining multiple dialysis patient populations into a single dialysis adequacy measure or by creating an additional exclusion for the PPPW clinical measure), and recommendations to change the ICH CAHPS survey to improve patients' response rates and reduce the associated provider burden by changing its administration. Commenters also urged CMS to be cognizant of the reporting burden imposed by quality measures and recommended aligning quality measures with other programs, using a single website to track and report performance data, and improving EHR data sharing.

Response: We thank the commenters for their recommendations and welcome feedback on ways to improve the program, including the adoption of new or revised measures. However, we note that these comments are not responsive to a proposal included in the CY 2020 ESRD PPS proposed rule, and therefore, are considered beyond the scope of the proposed rule.

1. Performance Standards for the PY 2022 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2019 ESRD PPS final rule (83 FR 57010), we set the performance period for the PY 2022 ESRD QIP as CY 2020 and the baseline period as CY 2018. In the CY 2020 ESRD PPS proposed rule (84 FR 38364), we estimated the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2022 clinical measures using data from 2016 and 2017, as shown in in Table 4. We also stated that we had proposed in the CY 2020 ESRD PPS proposed rule to convert the STrR measure from a clinical measure to a reporting measure and that if that proposal was finalized, we would not update these standards for the STrR measure.

TABLE 4: Estimated Performance Standards for the PY 2022 ESRD QIP Clinical Measures

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type			
Standardized Fistula Rate	52.61%	63.69%	76.11%
Catheter Rate	18.24%	11.15%	5.02%
Kt/V Comprehensive	92.98% (92.75%)*	96.88% (96.83%)*	99.14% (99.10%)*
Hypercalcemia	1.81%	0.57%	0.00%
Standardized Readmission Ratio	1.268 (1.273)*	0.998	0.629 (0.642)*
Standardized Transfusion Ratio	1.684 (1.695)*	0.840	0.194
NHSN Bloodstream Infection	1.477	0.694 (0.698)*	0
Standardized Hospitalization Ratio	1.248	0.967 (0.971)*	0.670 (0.687)*
PPPW	8.75%	17.77%	34.29%
ICH CAHPS: Nephrologists' Communication and Caring	58.09%	67.81%	78.53%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16%	62.34%	72.03%
ICH CAHPS: Providing Information to Patients	73.90% (73.89%)*	80.38%	87.08%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.85%)*	62.22% (60.37%)*	76.57% (74.50%)*
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (49.10%)*	63.04% (63.03%)*	77.48%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.97%)*	67.93%	82.48% (82.34%)*

* If the PY 2022 final numerical value is worse than the PY 2021 finalized value, we will substitute the PY 2022 final numerical value for the PY 2021 finalized value. We have provided the PY 2021 finalized value as a reference for clinical measures whose PY 2022 estimated value is worse than the PY 2021 finalized value.

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

We are now updating the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2022 clinical measures as shown in Table 5, using the

most recently available data, which includes CY 2018 data.[38] As discussed more fully in section IV.D.2.b of this final rule, we are finalizing our proposal to convert the STrR measure from a clinical measure to a reporting measure. Accordingly, we did not include the STrR clinical measure in Table 5.

TABLE 5: Finalized Performance Standards for the PY 2022 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	**Achievement Threshold (15th Percentile of National Performance)***	**Median (50th Percentile of National Performance)***	**Benchmark (90th Percentile of National Performance)***
Vascular Access Type			
Standardized Fistula Rate	52.52%	63.76%	76.16%
Catheter Rate	18.57%	11.22%	5.07%
Kt/V Comprehensive	93.10	97.04%	99.15%
Hypercalcemia	1.77%	0.58% (0.59%)	0.00%
Standardized Readmission Ratio	1.268 (1.269)	0.998	0.629 (0.641)
NHSN Bloodstream Infection	1.365	0.604	0
Standardized Hospitalization Ratio	1.248	0.967 (0.976)	0.670 (0.677)
PPPW	8.12%	16.73%	33.90%
ICH CAHPS: Nephrologists' Communication and Caring	58.12%	67.89%	78.52% (78.35%)
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16 (53.87%)	62.47%	72.11%
ICH CAHPS: Providing Information to Patients	74.09%	80.48%	87.14%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.92%)	62.22% (60.59%)	76.57% (75.16%)
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (48.59%)	63.04% (62.99%)	77.49%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.46%)	68.59%	83.03%
* If the PY 2022 final numerical value is worse than the PY 2021 finalized value, we will substitute the PY 2022 final numerical value for the PY 2021 finalized value. We have provided the PY 2021 finalized value as a reference in parentheses for clinical measures whose PY 2022 estimated value is			

38 In the CY 2020 ESRD PPS proposed rule (84 FR 38364), we inadvertently stated that the updated values would appear in the CY 2019 ESRD PPS final rule, instead of this final rule.

worse than the PY 2021 finalized value.

Data sources: VAT measures: 2018 CROWNWeb; SRR, SHR: 2018 Medicare claims; Kt/V: 2018 CROWNWeb; Hypercalcemia: 2018 CROWNWeb; NHSN: 2018 CDC; ICH CAHPS: CMS 2018; PPPW: 2018 CROWNWeb and 2018 OPTN.

In addition, we have summarized in Table 6 our finalized performance standards for the reporting measures in the PY 2022 ESRD QIP.

TABLE 6: Finalized Performance Standards for the PY 2022 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every HD Kt/V session during the week of the monthly Kt/V draw, and Kt/V date is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of BUN Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o ARNP, o PA, o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly data reported quarterly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and

	• pus, redness, or increased swelling at the vascular access site.
STrR	At least 10 patient-years at risk during the performance period.[39]

2. Update to the Scoring Methodology Previously Finalized for the PY 2022 ESRD QIP

a. Update to the Scoring Methodology for the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

We stated in the CY 2020 ESRD PPS proposed rule that there were two similar measures in the ESRD QIP that assess dialysis events: (1) the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, and (2) the NHSN Dialysis Event reporting measure. We stated that for the NHSN BSI clinical measure, facilities must be eligible to report 12 months of data to the NHSN on a quarterly basis in order to receive a score on the measure, and are scored based on whether they submitted data for that 12- month period and how many dialysis events they reported during that 12-month period. We stated that for the NHSN Dialysis Event reporting measure, facilities must enroll in the NHSN, complete any required training, and report monthly dialysis event data on a quarterly basis to the NHSN. We stated that the current scoring methodology for the NHSN Dialysis Event reporting measure was finalized in the CY 2017 ESRD PPS final rule (81 FR 77881), and it was selected for two reasons. First, due to the seasonal variability of bloodstream infection rates, we stated that we wanted to incentivize facilities to report the full 12 months of data and reward reporting consistency over the course of the entire performance period. Second, we stated that from the perspective of national prevention strategies and internal quality improvement initiatives, there was still value

39 In section IV.D.2.b of this final rule we finalized a policy to convert the STrR measure from a clinical measure to a reporting measure.

in collecting fewer than 12 months of data from facilities. For those reasons, we finalized a policy in the CY 2017 ESRD PPS final rule to award facilities 10 points for submitting 12 months of data, 2 points for reporting between 6 and 11 months of dialysis event data, and 0 points for reporting fewer than 6 months of data. See Table 7 for the scoring distribution finalized in the CY 2017 ESRD PPS final rule.

TABLE 7: Previously Finalized Scoring Distribution for the NHSN Dialysis Event Reporting Measure

Number of Reporting Months	Points Awarded to Facility
12 months	10 points
6-11 months	2 points
0-5 months	0 points

We stated in the CY 2020 ESRD PPS proposed rule (84 FR 38365) that as we have accumulated experience with this policy, we were concerned that new facilities and facilities for which CMS grants an ECE for part of the performance period that applies for a payment year were not eligible to receive a score on the NHSN Dialysis Event reporting measure because they were not eligible to report data for the full 12-month period. We stated that as a result, we did not believe that this policy appropriately accounted for the effort made by these facilities to report these data for the months in which they were eligible to report. For example, for PY 2020, the number of new facilities certified during the performance year (CY 2018) was 390 and the number of facilities granted an ECE during CY 2018 was 31, but none of those facilities was eligible to receive a score on the measure. We also stated our concern that if a facility was aware that it would not be eligible to receive a score on the NHSN Dialysis Event reporting measure, the facility would not be incentivized to report data at all for that payment year.

We stated that as a result of these concerns, we reconsidered our policy. We proposed to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12

eligible reporting months. Beginning with the PY 2022 ESRD QIP, we also proposed to assess successful reporting based on the number of months facilities are eligible to report the measure. Under this proposal, facilities would receive credit for scoring purposes based on the number of months they successfully report data out of the number of eligible months. For example, if a facility had 10 eligible reporting months because it was granted an ECE for 2 months of the performance period, and reported data for those 10 eligible months, the facility would receive a score, whereas under the current policy, the facility would not receive a score. To accommodate this proposed change and to ensure that our scoring methodology appropriately incentivizes facilities to report data on the NHSN Dialysis Event reporting measure, even if they are not eligible to report data for all 12 months of a performance period, we also proposed to assign scores for reporting different quantities of data as summarized in Table 8.

TABLE 8: Proposed Scoring Distribution for the NHSN Dialysis Event Reporting Measure

Percentage of Eligible Months* Reported	Points Awarded to Facility
100% of eligible months	10 points
Less than 100% but no less than 50% of eligible months	2 points
Less than 50% of eligible months	0 points

*We define the term "eligible months" to mean the months in which dialysis facilities are required to report dialysis event data to NHSN per the measure eligibility criteria. This includes facilities that offer in-center hemodialysis and facilities that treat at least 11 eligible in-center hemodialysis patients during the performance period.

We stated our belief that it was important to encourage new facilities and facilities with an approved ECE to report complete and accurate dialysis event data to the NHSN for all the months in which they are eligible to submit data so that we would have as comprehensive as possible a view of these facilities' performance on this important clinical topic. We stated our belief that complete and accurate reporting of NHSN data was critical to maintaining the integrity of the NHSN surveillance system, enabled facilities to implement their own quality improvement initiatives, and enabled the Centers for Disease Control and Prevention (CDC) to design and disseminate prevention strategies. We stated our belief that the fairest way to balance

these goals was to adopt a new NHSN Dialysis Event reporting measure policy focused more specifically on considering reporting successful based on the number of months that a facility is eligible to report the measure. We did not propose changes to the NHSN BSI clinical measure's scoring methodology and stated that we will continue to require that facilities report data for the full 12 months of data in order to receive a score on that measure.

The comments and our responses to the comments on the proposed updates to the NHSN Dialysis Event reporting measure's scoring methodology are set forth below.

Comment: Some commenters expressed support for the proposed change to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months. One commenter also supported CMS's proposal to assess successful reporting based on the number of months facilities are eligible to report the measure, stating that it is important to encourage facilities to submit dialysis event data that is as complete and accurate as possible. Another commenter recognized the importance of having complete NHSN data and incentivizing all facilities to submit data regardless of the number of months they are eligible to report. This commenter further agreed that there is value in having new facilities and facilities with an approved ECE report data. One commenter suggested that we submit the measure to NQF for its review.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS not finalize the proposed scoring distribution for the NHSN Dialysis Event reporting measure and recommended that CMS amend the scoring distribution for the NSHN Dialysis Event reporting measure so that facilities earn 10 points for 100 percent of eligible months; 8 points for reporting 80 percent or more eligible months but less than 100 percent of eligible months; 4 points for reporting 50 percent or more

eligible months but less than 80 percent of eligible months; and 0 points for reporting fewer than 50 percent of eligible months. Commenter stated that a facility that misses only 1 month of reporting will earn two points instead of the full ten points under the proposed scoring distribution and that such facilities should not be penalized so drastically. However, the commenter appreciates CMS' decision to allow facilities to receive credit on this measure based on the number of months they successfully report data out of the number of eligible months instead of penalizing new facilities unable to report for the full year and facilities with an approved ECE.

Response: We thank the commenter for its overall support of the proposal to allow new facilities and facilities with an approved ECE to receive credit for reporting data. We also thank the commenter for its suggested scoring distribution. However, we believe that the scoring methodology recommended by the commenter would allow facilities to be awarded too many points for reporting fewer than 100 percent of eligible months and could encourage facilities to pick and choose which months they want to report. We believe that our proposed methodology better incentivizes facilities to report data for all 12 months while also discouraging the selective suppression of data.

Final Rule Action: After considering public comments, we are finalizing the update to the scoring methodology for the NHSN Dialysis Event reporting measure as proposed.

b. Conversion of the Standardized Transfusion Ratio (STrR) Clinical Measure to a Reporting Measure

In the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197) we finalized the adoption of the Standardized Transfusion Ratio (STrR) clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP. We also finalized

policies to score facility performance on the STrR clinical measure based on achievement and improvement in the PY 2018 ESRD QIP final rule (79 FR 66209). We finalized identical scoring policies for the STrR clinical measure in the PY 2019 ESRD QIP and the PY 2020 ESRD QIP in the CY 2016 ESRD PPS final rule (80 FR 69060 through 69061) and the CY 2017 ESRD PPS final rule (81 FR 77916), respectively.

After finalizing the STrR clinical measure in the CY 2015 ESRD PPS final rule, we submitted the measure to the NQF for consensus endorsement, but the Renal Standing Committee did not recommend it for endorsement, in part due to concerns that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the measure rates. Upon reviewing the committee's feedback, we revised the STrR clinical measure's specifications to address those concerns. The updated measure specifications for the STrR clinical measure contain a more restricted definition of transfusion events than was previously used in the STrR clinical measure. Specifically, the revised definition excludes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying International Statistical Classification of Diseases and Related Health Problems—9 (ICD-9) or ICD—10 procedure code or value code. As a result, the measure can identify transfusion events more specifically and with less bias related to regional coding variation, which means that the measure assesses a smaller number of events as well as a smaller range of total events.

Following this revision, we resubmitted the STrR clinical measure (NQF #2979) to NQF for consensus endorsement. The NQF endorsed the revised STrR clinical measure in 2016, and in the CY 2018 ESRD PPS final rule (82 FR 50771 through 50774), we finalized changes to the STrR clinical measure that aligned the measure specifications used for the ESRD QIP with the

measure specifications that NQF endorsed in 2016 (NQF #2979), beginning with the PY 2021 ESRD QIP. We also finalized policies to score facility performance on the revised STrR clinical measure based on achievement and improvement (82 FR 50779 through 50780), and we subsequently finalized that those policies would continue for PY 2022 and in subsequent payment years (83 FR 57011).

Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the validity of the modified STrR measure (NQF #2979) finalized for adoption beginning with PY 2021. Commenters specifically stated that due to the new level of coding specificity required under the ICD-10-CM/PCS coding system, many hospitals are no longer accurately coding blood transfusions. The commenters further stated that because the STrR measure is calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals has negatively affected the validity of the STrR measure (83 FR 56993 through 56994).

In the CY 2020 ESRD PPS proposed rule (84 FR 38366), we stated that we are in the process of examining the concern raised by commenters about the validity of the modified STrR measure, and we stated that we had considered three alternatives for scoring the measure until we complete that process: (1) assign the score that a facility would need to earn if it performed at the 50th percentile of national ESRD performance during the baseline year to every facility that would otherwise earn a score during the performance period below that median score, (2) align the measure specifications with those used for the measure prior to the PY 2021 ESRD QIP, and (3) convert the STrR clinical measure to a reporting measure.

We stated that we had considered the second alternative because the previously adopted measure specifications for the STrR clinical measure include a more expansive definition of transfusions. However, we rejected the second policy alternative because that version of the

STrR clinical measure was not endorsed by the NQF due to the concern expressed by the Renal Standing Committee that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the measure rates. We stated that we are in the process of evaluating the concern raised by commenters to the CY 2019 ESRD PPS proposed rule, and we stated our intention to present our analyses and measure changes to the NQF under an ad hoc review of the STrR clinical measure later in the year before making a final decision regarding implementation in the ESRD QIP. Additionally, we stated that any substantive changes to the STrR measure that result from this process might require a MAP review prior to any future implementation effort. We stated that under the first policy alternative, the Program would continue use of a measure endorsed by NQF, and if a facility did receive a payment reduction, it would not be due to its performance on the STrR clinical measure. Facilities would have to score below the median score used in the minimum TPS (mTPS) for a different measure in order to receive a payment reduction. If a facility scored at the median used in the mTPS calculation for all measures, it would receive the same TPS as the mTPS and therefore would not receive a payment reduction. However, we stated that we rejected the first policy alternative because it would score facilities based on their performance on a measure whose validity we are currently examining.

We stated that under the third policy alternative, we would be using a reporting measure that is based on an NQF-endorsed measure, but we would not be scoring facilities on the measure based on their performance. While the concerns regarding measure validity might call into question the capacity for current data to adequately capture transfusion rates attributable to facilities, we stated our belief that the transfusions captured by the measure are a conservative estimate of the number of events that actually occur, and that those events represent an

undesirable health outcome for patients that is potentially modifiable by the dialysis facility through appropriate anemia management.

In light of the concerns raised about the validity of the STrR clinical measure, we stated that we are continuing to examine this issue. We stated our desire to ensure that the Program's scoring methodology results in fair and reliable STrR measure scores because those scores are linked to dialysis facilities' TPS and possible payment reductions. We stated our belief that the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that dialysis facilities are not adversely affected during our continued examination of the measure is to convert the STrR clinical measure to a reporting measure for the reasons discussed above.

We also proposed that, beginning with PY 2022, we would score the STrR reporting measure as follows: facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. We proposed that in order to receive 10 points on the measure, a facility would need to report the data required to determine the number of eligible patient-years at risk and have at least 10 eligible patient-years at risk. We stated that a patient-year at risk was a period of 12-month increments during which a single patient is treated at a given facility. A patient-year at risk can be comprised of more than 1 patient if, when added together, their time in treatment equals a year. For example, if 1 patient is treated at the same facility for 4 months and a second patient is treated at a facility for 8 months, then the two patients would combine to form a full patient year.

We stated our belief that this scoring adjustment policy would enable us to retain an anemia management measure in the ESRD QIP measure set while we continue to examine the

measure's validity concerns raised by stakeholders.

The comments and our responses to the comments on the proposal to convert the STrR measure from a clinical measure to a reporting measures are set forth below.

Comment: To ensure reporting accuracy of the STrR reporting measure, a commenter suggested that CMS apply an approach similar to that proposed for the NHSN Dialysis event measure. Commenter suggested that the STrR reporting measure should be based on the number of months a facility is eligible to report the measure.

Response: Unlike the NHSN Dialysis Event reporting measure, which is calculated using monthly data, the STrR reporting measure is calculated based on if a facility has at least 10 eligible patient-years at risk over a full year. Consequently, it is not feasible to calculate the STrR reporting measure using the number of months a facility is eligible to report the data.

Comment: Some commenters supported CMS's examination into the validity of the STrR measure and the proposal to convert it to a reporting measure. One commenter advised CMS to seek NQF review of the STrR clinical measure. Another commenter requested that CMS clarify and specify the STrR reporting requirements, including those pertaining to data elements, information submission, and the reporting schedule. One commenter suggested that the STrR clinical measure should only include patients who receive CKD anemia-related transfusions, given the number of acute and chronic conditions suffered by ESRD patients which may also necessitate a transfusion.

Response: We thank the commenter for its support of our proposal to convert the STrR clinical measure to a reporting measure. We agree with the commenter's recommendation to seek NQF review of the STrR clinical measure and have submitted the measure to NQF for review. Information gleaned from the review will be used to help support any future policies

related to the STrR clinical measure. We acknowledge the commenter's recommendation to provide additional clarity regarding the scoring methodology for the STrR reporting measure and have provided additional details below. We note that the measure specifications for the STrR reporting measure remain the same as those finalized in the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197). However, because we are finalizing that we will now score the measure as a reporting measure, we will no longer score the measure based on the actual clinical values reported by facilities. Rather, for the STrR Reporting measure, facilities with at least 10 patient-years at risk will receive a score of 10; facilities with fewer than 10 patient-years at risk will not be eligible to receive a score on the STrR reporting measure. Specifically, the calculation of a patient-year at risk excludes the time periods when:

1. Patients are less than 18 years old.

2. Patients are on ESRD treatment for fewer than 90 days.

3. Patients are on dialysis at the facility for fewer than 60 days

4. Time during which patients have a functioning kidney transplant (exclusion begins 3 days prior to the date of transplant).

5. Patients have not been treated by any facility for a year or longer.

6. Patients with a Medicare claim (Part A inpatient, home health, hospice, and skilled nursing facility claims; Part B outpatient and physician supplier) for one of the following conditions in the past year: hemolytic and aplastic anemia, solid-organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, or sickle cell anemia.

7. Patient-months not within two months of a month in which a patient has $900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim.

8. Patients beginning 60 days after they recover renal function or withdraw from dialysis. We also thank the commenter for its recommendation to include only patients who receive CKD anemia-related transfusions in the STrR clinical measure. We will assess the feasibility of this recommendation during our review of the STrR clinical measure.

Comment: Commenter expressed concern regarding the reliability and accuracy of the STrR clinical measure for small dialysis facilities, stating that it was often inappropriately scored. Commenter proposed removing the measure from the ESRD QIP until such issues are resolved.

Response: We thank the commenter for highlighting its concerns regarding the impact of the STrR clinical measure on small dialysis facilities. We will take this into account as we continue to examine the STrR clinical measure. In recognition of stakeholder concerns, we proposed to convert the STrR clinical measure to a reporting measure until all issues are resolved. We believe this approach allows us to continue assessing facilities on anemia management and avoid an adverse financial impact on facilities.

Comment: Commenter expressed concern regarding the validity of the STrR measure as a reporting measure, due to the accuracy difficulties presented by hospital coding practices. Commenter suggested that CMS adopt a risk-standardized rate measure as a potential alternative to submit for NQF endorsement.

Response: We disagree that variations in hospital coding practices would adversely impact facility performance on the STrR reporting measure. Based on the scoring methodology for the STrR reporting measure, facilities will receive 10 points on the measure if the facility

successfully reports data on the measure and has at least 10 patient-years at risk during the performance period. We disagree with the commenter's suggestion to consider a risk-standardized rate instead of a ratio for the STrR clinical measure. Placing a facility's risk adjusted rate in context requires reference to a standard rate that applies to the population as a whole. The utilization of a ratio allows us to compare 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.

Comment: Several commenters recommended that CMS examine whether a hemoglobin threshold measure could be used as possible alternative to the STrR clinical measure in the ESRD QIP to satisfy its statutory anemia management measure requirement. Some commenters recommended replacing the STrR clinical measure with a measure of hemoglobin less than 10 g/dL. The commenters stated that a hemoglobin less than 10 g/dL measure is supported by considerable evidence, is most actionable for dialysis providers, and is operationally feasible. One commenter stated that hemoglobin is routinely measured, and its elevation is the most proximate effect of ESA administration. The commenter further stated that low hemoglobin is a predictor of transfusion risk, and that a hemoglobin of 10 g/dL is an effective level for reducing the need for transfusions. Commenter stated that CMS's removal of the hemoglobin measure from the ESRD QIP in 2012 was due to inconsistency with ESA labeling that was revised in June 2011 and that while the measure's standard became inappropriate, the measure is valid and places adequate anemia treatment under dialysis facility control.

Response: Use of a hemoglobin threshold measure has been previously considered and was not implemented based on several concerns. First, studies reporting results of anemia management in chronic dialysis settings typically result in hemoglobin distributions with

relatively large outcome variation, creating concern that attempts at achievement of a specific target will result in a substantial minority of treated patients either well above or below the target at any point in time. Given the significant concerns about potential clinical risks of overtreatment with ESAs, implementation of a hemoglobin threshold could result in increased risk of ESA-related complication for the subset of patients above the threshold. One major consequence of under treatment is increased transfusion risk. Emphasis on minimizing avoidable transfusions in this population focuses on avoiding a major consequence of under-treatment without explicitly contributing to the risks associated with over-treatment with ESAs. This approach is consistent with the Food and Drug Administration (FDA) guidance for use of ESAs in this population. In addition, the available literature has not clearly established a minimum hemoglobin threshold that reliably maximizes the primary outcomes of survival, hospitalization, and quality of life for most patients. If new evidence becomes available, we will reassess the feasibility of replacing the STrR clinical measure with a hemoglobin measure as part of our future measure development work.

Comment: Commenter expressed concerns about the proposal to convert the STrR clinical measure to a reporting measure. Commenter agreed that facilities should not be adversely affected while CMS investigates the measure's validity concerns. However, the commenter expressed concerned about giving facilities credit for reporting a measure that is derived using hospital claims data and not values collected and reported in the facility. The commenter expressed concern that this approach stretches the ESRD QIP's statutory requirement to include a measure of anemia management to its limit. Commenter stated that CMS should examine anemia management practices in clinics through random audits or validation surveys to monitor compliance and identify signs of stinting.

Response: Anemia is a complication of end-stage renal disease that can be avoided if a patient's dialysis facility is undertaking proper anemia management. When anemia is not managed patients are subjected to unnecessary transfusions that increase morbidity and mortality. The STrR measure is calculated using data reported by hospitals because poor anemia management results in transfusions that most often occur in hospitals and not dialysis facilities. The commenter's recommendation to conduct random audits of anemia management practices is not feasible because we do not have the authority to examine anemia management practices in clinics through our validation activities. However, we will assess the feasibility of gathering more data about anemia management practices in clinics through our monitoring and evaluation work.

Comment: Commenter expressed concern that CMS may consider eliminating the STrR clinical measure from the ESRD QIP. Commenter advocated preserving the STrR clinical measure in the ESRD QIP in PY 2022 and beyond, emphasizing the importance of a measure monitoring anemia management. Acknowledging accuracy issues associated with the current STrR clinical measure, commenter suggested that CMS determine an appropriate measure of anemia management to incentivize reducing the need for transfusions.

Response: We agree that it is important to include a measure monitoring anemia management in the program. However, in light of concerns regarding the STrR clinical measure, we do not believe it is appropriate to potentially penalize facilities for their performance on the clinical measure while we examine concerns raised by stakeholders. We believe that converting the STrR clinical measure to a reporting measure is appropriate to ensure that facilities are not penalized for their performance. If we conclude that the concerns about the STrR clinical measure raised by stakeholders are not supported by the evidence, we will consider reintroducing

the measure or an updated version of the measure into the program through the rulemaking process.

Final Rule Action: After considering public comments, we are finalizing our proposals to convert the STrR clinical measure to a reporting measure and to update the scoring methodology as proposed.

c. MedRec Reporting Measure Scoring Methodology

In the CY 2019 ESRD PPS final rule (83 FR 57011), we finalized a policy to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP.

$$\left(\frac{\text{Number of patient-months successfully reporting data}}{\text{Number of eligible patient-months}} \text{ X } 12 \right) - 2$$

We also stated that this equation was similar to the equation used for the Ultrafiltration reporting measure (81 FR 77917):

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \text{ X } 12 \right) - 2$$

However, we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38367) that we inadvertently used the term "patient-months" in the MedRec reporting measure's scoring equation. We stated that we calculate a subset of our clinical measures using patient-months (the Kt/V Comprehensive clinical measure, the Standard Fistula Rate clinical measure, the Catheter Rate clinical measure, and the Hypercalcemia clinical measure) because patient-months is the unit of analysis based on their measure specifications. We stated that facility-months are generally used for a reporting measure because they assess the proportion of months in a year

that a facility reported to CMS the data necessary to calculate the measure.

We stated that the use of facility-months for the MedRec reporting measure is also consistent with the scoring methodology we have used for all other reporting measures which require monthly reporting, including the Anemia Management reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP), the Serum Phosphorus reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP measure), and the Ultrafiltration reporting measure.

We therefore proposed to revise the scoring equation for the MedRec reporting measure so that the scoring methodology accurately describes our intended policy. We proposed to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP. We solicited public comments on this proposal.

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \text{ X } 12 \right) - 2$$

Additionally, we stated that in section IV.B.4 of the CY 2019 ESRD PPS final rule, we had finalized a requirement for PY 2021 and beyond for facilities to begin collecting 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 CMS Certification Number (CCN) becomes effective (83 FR 56999 through 57000). In section IV.C.4.c of the CY 2019 ESRD PPS final rule, we also finalized a policy for the MedRec reporting measure to begin scoring facilities with a CCN Open Date before the January 1st of the performance period (83 FR 57011). In section IV.C.6 of the CY 2019 ESRD PPS final rule (83 FR 57013 through 57014), we applied the updated reporting

requirement for new facilities finalized in section IV.B.4 of the CY 2019 ESRD PPS final rule to the MedRec reporting measure eligibility requirements finalized in section IV.C.4.c of the CY 2019 ESRD PPS final rule. We specified in Table 23 of the CY 2019 ESRD PPS final rule that facilities with a CCN Open Date before October 1, 2019 would meet the eligibility requirements for the MedRec reporting measure.

In order to ensure that there is no confusion regarding these requirements, we clarified in the CY 2020 ESRD PPS proposed rule (84 FR 38367) that for the MedRec reporting measure, facilities with a CCN Open Date before the October 1st prior to the performance period (which, for the PY 2022 ESRD QIP, would be a CCN Open Date before October 1, 2019) must begin collecting data on that measure.

The comments and our responses regarding the MedRec reporting measure's scoring methodology updates are set forth below.

Comment: Some commenters expressed concerns with our proposal to change the term "patient-months: in the MedRec reporting measure's scoring equation to the term "facility months." Commenters stated that the term "patient-months" is more consistent with the NQF's definition, and disagreed with CMS's assertion that using "facility months" is more appropriate for a reporting measure. One commenter noted that this change could potentially result in lower scores for facilities that fail to perfectly report for all patients in all months. This commenter suggested that CMS use the "patient-month" metric used in the NQF-endorsed measure, or alternatively allow room for less than perfect reporting in the scoring equation.

Response: We acknowledge commenters' concerns and thank them for their feedback. While we reiterate our desire to align the scoring methodologies of all reporting measures, we also recognize the value of alignment with NQF measure specifications when possible and the

incorporation of more outcomes focused measures in ESRD QIP. As such, we have been persuaded by commenters' concerns and given that 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, we have decided to use "patient-months" instead of "facility months" when calculating "eligible months" for the MedRec measure. We believe this approach supports our desire to incorporate more outcomes-based measures in the ESRD QIP and is responsive to stakeholder concerns. We also plan to reevaluate other reporting measures for opportunities to more closely align them with NQF measure specifications.

Comment: One commenter supported the proposed change to the MedRec reporting measure scoring equation. Commenter agreed that MedRec is a reporting measure and should be scored like other reporting measures.

Response: We thank the commenter for its support of our proposal to score the MedRec measure consistent with how other reporting measures are scored. However, in recognition of stakeholder concerns regarding misalignment with the NQF endorsed measure specifications in addition to our desire to focus on more outcome-based measures, we plan to calculate the measure using patient months instead of facility months. This approach is aligned with our policy finalized in the CY 2019 ESRD PPS final rule (83 FR 57008 through 57010) and consistent with the NQF approved version of the measure.

Final Rule Action: After considering public comments, we are not finalizing the proposed update to the MedRec reporting measure's scoring methodology.

3. Update to the Eligibility Requirements for the PY 2022 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized a policy where, with respect to the

NHSN Dialysis Event reporting measure, facilities are required to have a CCN Open Date on or before the October 1 prior to the performance period to be eligible to receive a score, beginning with the PY 2021 ESRD QIP (83 FR 56999 through 57000). In section IV.B.3.a of the CY 2020 ESRD PPS proposed rule, we proposed to remove the NHSN Dialysis Event reporting measure's exclusion of facilities with fewer than 12 eligible reporting months and to assess successful reporting based on the number of months facilities were eligible to report the measure, beginning with the PY 2022 ESRD QIP. To accommodate this proposed policy, we proposed to remove the requirement that, to be eligible to receive a score on the NHSN Dialysis Event reporting measure, new facilities must have a CCN Open Date before October 1 prior to the performance period that applies to the payment year. We stated that Table 9 summarized the ESRD QIP's minimum eligibility requirements for scoring, including the proposed change to the eligibility requirement for the NHSN Dialysis Event reporting measure.

TABLE 9: Proposed Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (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 BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A as proposed	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)	10 patient-years at risk	N/A	N/A
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 prior to the performance period that applies to the program year.	N/A

Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

The comments and our responses regarding the minimum eligibility requirements are set forth below.

Comment: One commenter supported the removal of the CCN Open Date requirement for the Dialysis Event reporting measure. The commenter appreciated the interest in accurately capturing dialysis event data.

Response: We thank the commenter for its support of our proposal to remove the CCN Open Date requirement for the Dialysis Event reporting measure.

Comment: One commenter recommended that CMS give facilities a minimum of 90 days before being subject to the ESRD QIP's reporting requirements and exclude all facilities from ESRD QIP participation for the first 90 days after Medicare certification. Another commenter stated that new facilities have significant obligations when beginning operations and that they should not be penalized if they are unable to comply with CMS's reporting requirements.

Response: Under our current policy, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56669), new facilities are 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. We believe that this policy gives new facilities the flexibility they need to put into place the mechanisms needed in order to successfully participate in the ESRD QIP.

Final Rule Action: After considering public comments, we are finalizing as proposed the update to the NHSN Dialysis Event reporting measure's minimum eligibility requirements, which apply for the PY 2022 ESRD QIP and beyond.

4. Payment Reduction for the PY 2022 ESRD QIP

We stated in the CY 2020 ESRD PPS proposed rule that under our current policy, a facility will not receive a payment reduction in connection with its performance in the ESRD QIP for a payment year if it achieves a TPS that is at or above the minimum TPS that we establish for the payment year. We have defined the minimum TPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.[40]

We also stated that our current policy, which is codified at § 413.177 of our regulations, is also to implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum TPS (76 FR 634 through 635).

For PY 2022, we estimated using available data that a facility must meet or exceed a minimum TPS of 53 in order to avoid a payment reduction. We noted that the mTPS estimated in the CY 2020 ESRD PPS proposed rule was based on data from CY 2017 instead of the PY 2022 baseline period (CY 2018) because CY 2018 data were not yet available.

[40] We recently codified definitions for the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively. When we codified the definition of the "performance standard," we declined to include a reference to the 50th percent of national performance in that definition because the term "performance standards" applies more broadly to levels of achievement and improvement and is not a specific reference to the 50th percentile of national performance. Instead, we have incorporated the concept of the 50th percentile of national performance into the recently codified definition of the minimum TPS.

We referred the reader to Table 4 for the estimated values of the 50th percentile of national performance for each clinical measure. We stated in the CY 2020 ESRD PPS proposed rule that under our current policy, a facility that achieves a TPS below 53 would receive a payment reduction based on the TPS ranges indicated in Table 10.

TABLE 10: Estimated Payment Reduction Scale for PY 2022

Total performance score	**Reduction (%)**
100-53	0%
52-43	0.5%
42-33	1.0%
32-23	1.5%
22-0	2.0%

We stated our intention to update the minimum TPS for PY 2022, as well as the payment reduction ranges for that payment year, in the CY 2020 ESRD PPS final rule.

The comments and our responses regarding the mTPS and payment reduction scale are set forth below.

Comment: One commenter stated that ESRD QIP penalties do not align with actual performance and are problematic in a program designed to only apply payment penalties. The commenter also expressed concern about the percentage of facilities anticipated to face penalties in PY 2020 and PY 2021 given that facility performance is improving overall.

Response: We thank the commenters for their feedback. However, we disagree that ESRD QIP penalties do not align with actual performance as our measure set assesses the degree to which evidence-based treatment guidelines are followed and assess the results of care. While we recognize the commenters concerns regarding the increase in payment penalties, our adoption of several outcome and patient experience of care measures (such as the STrR 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 alignment with our meaningful measures initiative and measure removal criteria (83 FR 56983 through 56989). We believe that some increases in payment penalties are inevitable as the Program's measure set changes, particularly as we accumulate sufficient data on reporting measures and convert them to more outcomes based measures or as actual performance data on new measures become available to establish real and not estimated performance standards. Because of these policy changes, we believe it is reasonable for the payment reductions to shift even if performance on some measures is comparatively high. Nevertheless, we will continue monitoring the amount of payment penalties imposed on facilities and facilities performance on our quality measures.

Comment: One commenter recommended that CMS share details about the methodology used to project payment adjustments. Commenter expressed concern regarding the lack of transparency in CMS's methodology for penalty projections. Commenter expressed concerns that the ESRD QIP has grown more complex over time and that relatively small changes to the Program can significantly change the distribution of payment penalties. Commenter stated that its analysis of the STrR proposal, for example, shows that the proposal resulted in a significant change in the number of facilities projected to receive a penalty in PY 2022. Commenter noted that CMS has implicitly acknowledged validity concerns based on its proposal to make data validation activities permanent.

Response: We describe the methodology used to project payment adjustments for the ESRD QIP in the Regulatory Impact Analysis section of both the ESRD PPS proposed and final

rules each year. The most recent analyses, which apply to the PY 2022 and PY 2023 ESRD QIP, appeared in section XI.B.3.a of the CY 2020 ESRD QIP proposed rule and is in section X.B.3.b of this final rule. We calculate our projections by using the most recently available CROWNWeb and Medicare claims data. The list of eligible facilities is determined using the most recently published PPS eligible facility list. Simulated achievement scores are calculated using the achievement threshold and benchmark for each clinical measure. We use the achievement threshold and benchmark from the previous calendar year final rule rather than the standards published in the most current rule in order to simulate improvement in performance that we observe for some of the clinical measures from one year to the next. Improvement scores are calculated using the same methodology comparing the facility's performance year measure rate to the rate in the year prior. In the simulation, the performance year is based on the most recently available data, which will be at least 2 years prior to the actual performance year. Once the facility-level achievement and improvement scores are calculated, the measure weights are applied and the Total Performance Score is calculated. If a facility is missing one or more measures, then the measure weight(s) for the missing measures are redistributed to the other measures, based on the methodology proposed in the rule. For PY 2022 and PY 2023, the measure weights are redistributed equally among all other measures in the same domain. If we do not have data for a measure that is new to the ESRD QIP (for example, MedRec for PY 2022), we set the measure score to missing for all facilities and redistribute that weight equally among all other eligible measures in the same domain.

Finally, payment reductions are estimated using the mTPS that we calculate using the performance standards published in the previous year's final rule. Oftentimes the simulated mTPS is the same as the final mTPS proposed in the current rule, but we use an estimated

simulated mTPS in order to simulate the differences in performance in prior years. Additionally, the methodology used to estimate performances scores is consistent with how the actual facility payment reductions are determined, which use the mTPS, achievement threshold, and benchmark that are determined using data from the same year.

At the time the proposed rule was published, the most recently available data for a complete year was CY 2017. We have now updated the payment reductions that will apply to the PY 2022 ESRD QIP using CY 2018 data. The mTPS for PY 2022 will be 54, and the updated payment reduction scale is shown in Table 11.

TABLE 11: Finalized Payment Reduction Scale for PY 2022 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-54	0%
53-44	0.5%
43-34	1.0%
33-24	1.5%
23-0	2.0%

5. Data Validation for PY 2022 and Beyond

In the CY 2020 ESRD PPS proposed rule (84 FR 38368), 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. We stated that the ESRD QIP includes two validation studies for this purpose: the CROWNWeb data validation study (OMB Control Number 0938-1289) and the NHSN validation study (OMB Control Number 0938-1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb data validation study as a permanent feature

of the Program (83 FR 57003). We stated that under that policy, we will continue validating CROWNWeb data in PY 2022 and subsequent payment years, and we will deduct 10 points from a facility's TPS if it is selected for validation but does not submit the requested records.

We also adopted a methodology for the PY 2022 NHSN validation study, which targets facilities for NHSN validation by identifying facilities that are at risk for under-reporting. A sample of 300 facilities will be selected, and each facility will be required to submit 20 patient records covering 2 quarters of data reported in the performance year (for PY 2022, this would be CY 2020). For additional information on this methodology, we referred readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

In the CY 2020 ESRD PPS proposed rule, we proposed to continue using this methodology for the NHSN validation study for PY 2023 and subsequent years because based on a recent statistical analysis conducted by the CDC, we have concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities. We stated that this sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on those results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP are accurate, we proposed to continue use of this methodology in the PY 2023 NHSN validation study and for subsequent years.

Additionally, as we finalized for CROWNWeb validation, we proposed to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and proposed to continue for PY 2023 and subsequent years. We stated our belief that the purpose of our validation programs is to ensure the accuracy and completeness of data that are scored under the ESRD QIP and that validating NHSN data using this methodology achieves

that goal. Now that we have adopted a larger sample size of 300 facilities for the NHSN validation study and have thus ensured enough precision within the study, we believe that making the validation study permanent will show our commitment to accurate reporting of the important clinical topics covered by the NHSN measures that we have adopted. We welcomed public comments on these proposals.

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

Comment: Some commenters supported continued use of the CROWNWeb validation study and the 10-point non-compliance penalty. One commenter also supported the permanent adoption of the NHSN validation methodology and the continued use of the PY 2022 methodology in future payment years.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS adopt an alternative data validation approach, such as requesting data that only applies to the specific area of the validation, giving facilities more time to comply with data requests, and using electronic data exchange. The commenter expressed concerns about the burden placed on facilities to conduct data validation activities. The commenter also stated that CMS is not considering facility burden for validation activities.

Response: We will consider these recommendations during future rulemaking. Our validation studies are conducted within a timeframe that is consistent with our operational schedule. Currently facilities are given 60 days to respond to data request. We do not believe that increasing the time is feasible because our goal is to provide facilities with timely feedback about reporting accuracy. We disagree with the characterization that CMS is not taking facility

burden into consideration for these validation activities. Each year we calculate facility burden associated with our validation activities and submit this information as part of our Paperwork Reduction Act (PRA) submission package. For example, in our most recent PRA package, we estimated that the burden associated with the collection of information for our PY 2022 NHSN validation activities is 10 hours annually and $423 per facility, which we believe is a minimal burden on facilities. Additionally, given that our validation activities are widely supported by stakeholders and encourage improvements in data completeness and accuracy, we believe the value of our validation activities outweigh the current estimated burden posed on facilities. Currently, our validation activities are restricted to measures that utilize CrownWeb or NHSN as their primary data sources. If we impose further restrictions on data collected for validation actions, our ability to measure the accuracy of data submitted to CROWNWeb or NHSN will be severely limited. We also encourage facilities to submit data electronically through our secured transfer file system instead of submitting hard copies of requested records. We believe this approach is more efficient and effective for facilities.

Final Rule Action: After consideration of public comments we received, we are finalizing as proposed the continuation of the PY 2022 NHSN validation study methodology in PY 2023 and subsequent years as well as adoption of the NHSN validation study as a permanent feature of the Program.

E. Requirements for the PY 2023 ESRD QIP

1. Continuing Measures for the PY 2023 ESRD QIP

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that, under our previously adopted policy, we were continuing all measures from the PY 2022 ESRD QIP for PY 2023. We did not propose to adopt any new measures beginning with the PY 2023 ESRD

QIP.

2. Proposed Performance Period for the PY 2023 ESRD QIP and Subsequent Years

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated our continued belief that 12-month performance and baseline periods would provide us sufficiently reliable quality measure data for the ESRD QIP. We therefore proposed to establish CY 2021 as the performance period for the PY 2023 ESRD QIP for all measures. Additionally, we proposed to establish CY 2019 as the baseline period for the PY 2023 ESRD QIP for all measures for purposes of calculating the achievement threshold, benchmark, and minimum TPS, and CY 2020 as the baseline period for the PY 2023 ESRD QIP for purposes of calculating the improvement threshold. Beginning with PY 2024, we proposed to adopt automatically a performance and baseline period for each year that is 1-year advanced from those specified for the previous payment year. For example, under this policy, we would automatically adopt CY 2022 as the performance period for the PY 2024 ESRD QIP. We would also automatically adopt CY 2020 as the baseline period for purposes of calculating the achievement threshold, benchmark, and minimum TPS and CY 2021 as the baseline period for purposes of calculating the improvement threshold, for the PY 2024 ESRD QIP. We welcomed public comments on these proposals.

The comments and our responses to the comments on our proposals for establishing the performance and baseline periods are set forth below.

Comment: One commenter expressed support for CMS's proposal to codify the automatic adoption of a baseline period and a performance period for each payment year that is 1-year advanced from those specified for the previous payment year. The commenter also expressed its appreciation for the predictability and efficiency provided by this proposal.

Response: We thank the commenter for its support.

Final Action Decision: After considering public comments received, we are finalizing our proposals for establishing the performance and baseline periods as proposed.

3. Performance Standards for the PY 2023 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we referred readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We stated that we recently codified definitions for the terms "achievement threshold," "benchmark," "improvement threshold," and "performance standard" in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2023 ESRD QIP

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that at that time, we did not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we did not have CY 2019 data. We stated our intention to publish these numerical values, using CY 2019 data, in the CY 2021 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2023 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting

measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that we would continue use of those performance standards in PY 2023.

4. Scoring the PY 2023 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(d).[41]

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that we were not proposing to change these scoring policies.

b. Scoring Facility Performance on Reporting Measures

In the CY 2019 ESRD PPS final rule, we codified our policy for scoring performance on reporting measures at § 413.178(d),[42] and we finalized the continued use of existing policies for scoring performance on the Ultrafiltration Rate reporting measure and the MedRec reporting measure (83 FR 57011). In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that we would continue use of the Ultrafiltration Rate reporting measure's scoring policy in PY 2023. In section IV.B.3.c of the CY 2020 ESRD PPS proposed rule, we proposed to use facility-months instead of patient-months when scoring the MedRec reporting measure and clarified our intention to begin scoring new facilities with a CCN Open Date before the October 1st of the year prior to the performance period rather than before the January 1st of the

[41] Please note that we are finalizing our proposal to redesignate § 413.178(d) as § 413.178(e) in this final rule.
[42] Please note that we are finalizing our proposal to redesignate § 413.178(d) as § 413.178(e) in this final rule.

performance period. We stated in the CY 2020 ESRD PPS proposed rule that those proposals, if finalized, would apply to PY 2023 and subsequent payment years. In Section IV.D.2.c of this final rule, we did not finalize our proposal to update the scoring methodology for the MedRec reporting measure, so that measure will be scored in accordance with the methodology we finalized in the CY 2019 ESRD PPS final rule. (83 FR 57008 through 57010).

5. Weighting the Measure Domains and the TPS for PY 2023

In the CY 2020 ESRD PPS proposed rule (84 FR 38369), we stated that under our current policy, we have assigned the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS, for the PY 2022 ESRD QIP (83 FR 57011 through 57012).

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures in the PY 2022 ESRD QIP (83 FR 57011 through 57012). In the CY 2020 ESRD PPS proposed rule (84 FR 38370), we proposed to continue use of the PY 2022 measure weights for the PY 2023 ESRD QIP and subsequent payment years. We also proposed to continue use of the PY 2022 measure weight redistribution policy in the PY 2023 ESRD QIP and subsequent payment years. We solicited public comments on these proposals.

We also noted that under our current policy, a facility must be eligible to be scored on at least one measure in two of the four measures domains in order to be eligible to receive a TPS (83 FR 57012).

The comments and our responses to the comments on our measure weight assignments

and weight redistribution proposals are set forth below.

Comment: One commenter expressed concern with the weight of the MedRec reporting measure within the Safety Measure Domain, and its application to home dialysis facilities. The commenter noted that because other measures within the domain do not apply to home dialysis facilities, the MedRec reporting measure effectively has more weight in the ESRD QIP TPS than otherwise intended. To remedy this concern, commenter suggested that CMS move the MedRec reporting measure from the Safety Measure Domain to the Care Coordination Measure Domain. The commenter also suggested that CMS add the following patient-level exclusions for home dialysis facilities: (1) patients not assigned to the facility for the entire reporting month, and (2) patient-months where there is a more than one treatment modality.

Response: In the CY 2019 ESRD PPS final rule (83 FR 57003 through 57010), we finalized the MedRec reporting measure for the ESRD QIP measure set, beginning with PY 2022. The MedRec reporting measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the dialysis patient population because those patients typically take a large number of medications. Inclusion of the MedRec measure in the ESRD QIP measure set aligns with the Meaningful Measure Initiative priority area of making care safer by reducing harm caused by care delivery. As noted in the CY 2019 ESRD PPS final rule, 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. While it is possible that MedRec will be weighted more for home dialysis facilities, we do not believe this is inappropriate because regardless of the facility type, all facilities are required to provide high quality services to patients that do not cause harm. Additionally, in accordance with our monitoring and evaluation efforts, we plan to monitor the

impact of measures on dialysis facilities and the quality of care provided to facilities and propose any changes we think are warranted. We thank the commenter for its recommendation regarding patient-level exclusions to the measure; however these comments are out of scope given that we are not proposing to make any updates to the underlying measure specifications. Nevertheless, we will review and assess the feasibility of the commenter's recommendation and if warranted, consider in future rulemaking.

Comment: One commenter expressed concern that the current weighting of measure domains, given the increasing number of quality measures, may dilute the importance of each individual measure and potentially result in decreased quality of care. The commenter recommended that we continually reevaluate the ESRD QIP to ensure that the measures included are all meaningful. Another commenter stated that the weighting assigned to the SRR and SHR measures (12 percent each) is too high given the amount of control that dialysis facilities have over admissions and readmissions to the hospital. The commenter stated that we should reduce the weights assigned to those measures and increase the weighting applied to measures in the Clinical Care and Safety domains.

Response: We disagree that our current measure domains and weighting dilutes the importance of each individual measure and decreases quality of care. We believe our core set of measures addresses areas that are agency priorities, safeguard public health, and are meaningful to patients. Further, we take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, patient and provider burden) the number of measures and measure topics in the domain, how much experience facilities have had with the measures and measure topics in the domain, and how well the measures align with CMS's highest priorities for quality improvement

from patients receiving dialysis. We also continuously review our existing measures and weights and propose changes that we think are warranted. We disagree with the commenter's recommendation to reduce the weight of SHR and SRR. We believe that our weights for SRR and SHR are appropriate given that reducing hospitalizations and readmission is a top policy goal for CMS. We also continue to believe that the SHR and SRR measures, along with other measures in the ESRD QIP, ensure that dialysis facilities fulfill their shared responsibilities to coordinate with other types of providers to provide the best possible care and ensure their patients' continued health.

Comment: Commenter requested clarification on how the TPS would be reweighted for facilities that are unable to reach the required 30 ICH-CAHPS survey count. Commenter suggested that many facilities will not receive ICH-CAHPS scores and noted that the additional clarity would be helpful to those facilities.

Response: In the CY 2019 ESRD PPS final rule (83 FR 56998), we finalized a policy that would redistribute the weights of any measures for which the facility does not receive a score to the remaining measures proportionately based on their measure weight as a percent of the TPS. This redistribution would occur across all measures regardless of their domain. 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 and evenly split among measures within each domain. We believe this approach addresses concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures.

Final Rule Action: After considering the public comments we received, we are finalizing as proposed continuation of the PY 2022 measure weights in PY 2023 and subsequent payment

years as well as our continued use of the PY 2022 weight redistribution policy in PY 2023 and subsequent payment years.

V. Establishing Payment Amounts for New Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Items and Services (Gap-filling)

A. Background

1. Calculating Fee Schedule Amounts for DMEPOS Items and Services

Section 1834(a) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for DME other than customized items defined at 42 CFR 414.224 and items included in a competitive bidding program and furnished in a competitive bidding area under section 1847(a) of the Act. Section 1834(h) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for most prosthetic devices, orthotics, and prosthetics other than off-the-shelf orthotics included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act. Section 1834(i) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount for surgical dressings. Section 1833(o)(2)(A) of the Act mandates payment based on the lesser of the supplier's actual charge or a fee schedule amount in accordance with section 1834(h) of the Act for custom molded shoes, extra-depth shoes, and inserts. Section 1842(s) of the Act authorizes payment based on the lesser of the supplier's actual charge or a fee schedule amount for parenteral and enteral nutrients, equipment, and supplies (PEN), other than enteral nutrients, equipment, and supplies included in a competitive bidding program in a competitive bidding area under section 1847(a) of the Act, and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office. The fee schedule amounts established for these items and services are based on payments made

previously under the reasonable charge payment methodology, which is set forth in section 1842(b) of the Act and in our regulations at 42 CFR 405.502. Generally, reasonable charge determinations are based on customary and prevailing charges derived from historic charge data. The fee schedule amounts for DME, prosthetic devices, orthotics, prosthetics, and custom molded shoes, extra-depth shoes, and inserts are based on average reasonable charges from 1986 and 1987. The fee schedule amounts for surgical dressings are based on average reasonable charges from 1992. The fee schedule amounts for PEN are calculated on a nationwide basis and are the lesser of the reasonable charges for 1995, or the reasonable charges that would have been used in determining payment for these items in 2002 under the former reasonable charge payment methodology (§ 414.104(b)). The fee schedule amounts for splints and casts are based on reasonable charges for 2013 and the fee schedule amounts for intraocular lenses inserted in a physician's office are based on reasonable charges for 2012. Pursuant to sections 1834(a)(14)(L), 1834(h)(4)(xi), and 1842(s)(1)(B)(ii) of the Act, the DMEPOS fee schedule amounts are generally adjusted annually by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding year reduced by a productivity adjustment. The Medicare payment amount for a DMEPOS 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 Medicare 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.

The statute does not specify how to calculate fee schedule amounts when the base reasonable charge data does not exist. As discussed later on, since 1989, we have used a process referred to as "gap-filling" to fill the gap in the reasonable charge data for new DMEPOS items, which are newly covered items or technology. The gap-filling process is used to estimate what

Medicare would have paid for the item under the reasonable charge payment methodology during the period of time from which reasonable charge data is used to calculate the fee schedule amounts, or the fee schedule "base period" (for example, 1986 and 1987 for DME). Various methods have been used by CMS and its contractors to gap-fill DMEPOS fee schedule amounts including use of fees for comparable items, supplier prices, manufacturer's suggested retail prices (MSRPs), wholesale prices plus a markup percentage to convert the prices to retail prices, or other methods. In any case where prices are used for gap-filling, the prices are deflated to the fee schedule base period by the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the price is in effect to the mid-point of the fee schedule base period. Program guidance containing instructions for contractors (mainly for use by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs)) for gap-filling DMEPOS fee schedule amounts is found at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100-04). The instructions indicate that the DMEPOS fee schedule for items for which reasonable charge data were unavailable during the fee schedule base period are to be gap-filled using the fee schedule amounts for comparable items or supplier price lists with prices in effect during the fee schedule base period. The instructions specify that supplier price lists include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data (for example, fee schedule amounts comprised of the median of the commercial pricing information adjusted as described below). Mail order catalogs are suitable sources of routinely available price information for items such as urological and ostomy supplies which require frequent replacement. We issued

Transmittal 4130, Change Request 10924 dated September 14, 2018 which updated the manual instruction to clarify that supplier price lists can include internet retail prices or verifiable information from supplier invoices and non-Medicare payer data. Prior to 2018, non-Medicare payer data had not been included to establish gap-filled DMEPOS fee schedule amounts. CMS and its contractors have used internet retail prices in the past in addition to catalog prices, as well as wholesale prices plus a retail price mark up, and on one occasion hospital invoices plus a 10 percent markup as a source for commercial pricing information.

In 2015, when revising the DME MAC statement of work, CMS clarified to the DME MACs that MSRP should not be used for gap-filling due to CMS's concerns that MSRPs may not represent routinely available supplier price lists, which are incorporated for supplier charges in calculating fee schedule amounts that the statute mandates be based on historic reasonable charges. Although MSRPs were used in certain cases in the past to gap-fill DMEPOS fee schedule amounts, our experience has revealed the retail prices suggested by manufacturers often are inflated and do not reflect commercial competitive pricing, or a price that is paid to a supplier for furnishing items and services. Using MSRPs to gap-fill DMEPOS fee schedule amounts led to excessive fee schedule amounts compared to fees established for other DMEPOS items paid for in 1986, 1987, 1992, 2001, or other fee schedule base periods. In some cases, a single manufacturer may produce a new item, and pricing information may therefore be limited to the MSRP. In these cases, unlike other items and services paid for under Medicare, there is not yet independently substantiated pricing information. In addition, similar items may not be available to create competition and to potentially limit the price a sole source manufacturer charges for the new item. We believe the MSRP may represent the amount the manufacturer charges to Medicare and other health insurance payers before pricing is established in a competitive market

by suppliers furnishing the product and competitor products.

Currently, when we release our program instruction announcing updates to the DMEPOS fee schedule, we include a list of new Healthcare Common Procedure Coding System (HCPCS) codes, which are added to the DMEPOS fee schedule. Also, we release updated DMEPOS fee schedule amounts in fee schedule files to our contractors and available online at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html.

If a HCPCS code for a new item is added and takes effect, and the fee schedule amounts for the new code have not yet been added to the DMEPOS fee schedule file, our contractors establish payment on an interim basis using local fee schedule amounts gap-filled in accordance with the program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual until the fee schedule amounts on the national files are available.

2. Coding for New DMEPOS Items

The HCPCS is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs. Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes identifying primarily medical services and procedures furnished by physicians and other health care practitioners, published and maintained by the American Medical Association. Level II of the HCPCS codes primarily identifies items, supplies, services and certain drugs used outside the practitioner setting. Assignment of a HCPCS code is not a coverage determination and does not imply that any payer will cover the items in the code category.

In 2001, section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) mandated the establishment of procedures

for coding and payment determinations for new DMEPOS items under Medicare Part B that permit public consultation in a manner consistent with the procedures established for implementing ICD–9–CM coding modifications. As a result, beginning in 2002, after the HCPCS Workgroup has developed its preliminary decision, these preliminary decisions are made available to the public via our website and public meetings are scheduled to receive public comment on the preliminary decisions.

Following the HCPCS public meetings, we make a final decision on each new DMEPOS code request and payment category. Then, we prepare and release the HCPCS and DMEPOS fee schedule files and program instructions for the next update (annual or quarterly) to our contractors and via our website for public access. Also, a summary of the final coding and payment category decisions is made available on our website. See the following websites for more information:

- HCPCS Files: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html;
- DMEPOS Fee Schedule Files: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html;
- Program Instructions: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html; and
- Public Meeting Summaries: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html.

Typically, more than 100 applications are submitted to the CMS HCPCS Workgroup each year, with approximately one-third requesting new or revised DMEPOS codes. The list of approved new DMEPOS codes is not finalized until shortly before the release of the updated HCPCS file, which in some cases, leaves very short timeframes to prepare and release the updated DMEPOS fee schedule.

3. Continuity of Pricing

Instructions for contractors addressing how to establish DMEPOS payment amounts following updates to HCPCS codes are contained at section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. When an item receives a new HCPCS code, it does not necessarily mean that Medicare payment on a fee schedule basis has never been made for the item described by the new code. If a new code is established, CMS and our contractors follow the instructions in section 60.3.1 to make every effort to determine whether the item has a pricing history. If there is a pricing history, that is, the item(s) and services described by the new code were paid for in the past under existing codes based on the fee schedule amounts for these codes, the fee schedule amounts previously used to pay for the item are mapped or cross walked to the new code(s) for the item to ensure continuity of pricing. Since there are different kinds of coding changes, there are various ways pricing is cross walked from old codes to new codes, which are addressed in our program instructions at section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. For example, when the code for an item is divided into multiple codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. However, when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts for the single code are applied to each of the new codes. Conversely, when the codes for the components of an item are combined in a single global code, the fee schedule amount for the new code is established by totaling the fee schedule amounts used for the components (that is, the total of the fee schedule amounts for the components is used to determine the fee schedule amount for the global code). However, when the codes for several

different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes. These instructions are used to ensure continuity of pricing under the Medicare program, but do not apply to items when a pricing history does not exist, that is, in situations where an item was not paid for under a HCPCS code or codes with an established DMEPOS fee schedule amount(s). The gap-filling process only applies to items not assigned to existing HCPCS codes with established fee schedule amounts and items that were not previously paid for by Medicare under either a deleted or revised HCPCS code.

4. Authority for Establishing Special Payment Limits

Section 1842(b)(8) of the Act authorizes CMS to adjust payment amounts if, subject to the factors described in the statute and the regulations, CMS determines that such payment amounts are grossly excessive or grossly deficient, and therefore are not inherently reasonable. CMS may make a determination that would result in an increase or decrease of more than 15 percent of the payment amount for a year only if it follows all of the requirements under paragraphs (B), (C), and (D) of section 1842(b)(8) of the Act. Under these requirements, CMS must take certain factors into account, such as whether the payment amount does not reflect changing technology. In addition, section 1842(b)(9) of the Act mandates a specific process that CMS must follow when using this "inherent reasonableness" authority (IR authority) to adjust payment amounts by more than 15 percent a year. CMS has established the methodology and process for using the IR authority at §§ 405.502(g) and (h). Use of the IR authority involves many steps mandated under sections 1842(b)(8) and (9) of the Act, which can include consulting with supplier representatives before making a determination that a payment amount is not

inherently reasonable; publishing a notice of a proposed determination in the **Federal Register** which explains the factors and data taken into account; a 60-day comment period; and publishing a final notice, again explaining the factors and data taken into account in making the determination. Medicare can only make payment adjustments for "inherent reasonableness" that would result in a change of more than 15 percent per year by going through the process outlined in the statute and at §§ 405.502(g) and (h). As a result, the requirements under sections 1842(b)(8) and (9) of the Act regarding "inherent reasonableness" adjustments are applicable to special payment limits established in cases where supplier or commercial prices used for gap-filling decrease by more than 15 percent.

Examples of factors that may result in grossly excessive or grossly deficient payment amounts are set forth at § 405.502(g)(1)(vii) and include, but are not limited to, the following:

- The market place is not competitive.
- Medicare and Medicaid are the sole or primary sources of payment for a category of items and services.
- The payment amounts for a category of items and services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.
- The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services.
- Payment amounts for a category of items and services are grossly higher or lower than acquisition or production costs for the category of items and services.

- There have been increases in payment amounts for an item or service that cannot be explained by inflation or technology.
- Payment amounts for a category of items or services are grossly higher or lower than payments made for the same category of items or services by other purchasers in the same locality.
- A new technology exists which is not reflected in the existing payment allowances.

Prior to making a determination pursuant to section 1842(b)(8) of the Act that would result in an increase or decrease of more than 15 percent in a payment amount for a year, CMS is required to consult with representatives of suppliers or other individuals who furnish an item or service. In addition, section 1842(b)(8)(D) of the Act mandates that CMS consider the potential impact of a determination pursuant to section 1842(b)(8) that would result in a payment amount increase or decrease of more than 15 percent for a year on quality, access, beneficiary liability, assignment rates, and participation of suppliers. In establishing a payment limit for a category of items or services, we consider the available information relevant to the category of items or services in order to establish a payment amount that is realistic and equitable. Under § 405.502(g)(2), the factors we may consider in establishing a payment limit include the following:

- Price markup. The relationship between the retail and wholesale prices or manufacturer's costs of a category of items and services. If information on a particular category of items and services is not available, we may consider the price markup on a similar category of items and services and information on general industry pricing trends.

- Differences in charges. The differences in charges for a category of items and services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.
- Costs. Resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items and services.
- Use. Imputing a reasonable rate of use for a category of items or services and considering unit costs based on efficient use.
- Payment amounts in other localities. Payment amounts for a category of items and services furnished in another locality.

In determining whether a payment amount is grossly excessive or grossly deficient, and in establishing an appropriate payment amount, we use valid and reliable data. To ensure the use of valid and reliable data, we must meet the criteria set forth at § 405.502(g)(4), to the extent applicable. This includes, but is not limited to, considering the cost of the services necessary to furnish a product to beneficiaries if wholesale costs are used.

If we make a determination that a special payment limit is warranted to adjust a grossly excessive or grossly deficient payment amount for a category of items and services by more than 15 percent within a year, we must publish in the **Federal Register** a proposed and final notice of any special payment limits before we adopt the limits, with at least a 60-day period for public comments on the proposed notice. The proposed notice must explain the factors and data considered in determining the payment amount is grossly excessive or deficient and the factors and data considered in determining the special payment limits. The final notice must explain the factors and data considered and respond to public comment.

5. The 2006 Proposed Rule and 2018 Solicitation of Comments on Gap-Filling

On May 1, 2006, we published several proposed changes for the gap-filling process in our rule titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (71 FR 25687 through 25689). The May 2006 proposed rule discussed the existing gap-filling process and the results of pilot assessments conducted by two CMS contractors to assess the benefits, effectiveness, and costs of several products. The purpose of the pilot assessments was to compile the technical information necessary to evaluate the technologies of the studied products with the objective of making payment and HCPCS coding decisions for new items. The contractors evaluated the products based on: (1) a functional assessment; (2) a price comparison analysis; and (3) a medical benefit assessment. The functional assessment involved evaluating a device's operations, safety, and user documentation relative to the Medicare population. The price comparison analysis involved determining how the cost of the product compared with similar products on the market or alternative treatment modalities. The medical benefit assessment focused on the effectiveness of the product in doing what it claims to do.

As a result of the pilot studies, we proposed to use what we referred to as the "functional technology assessment" process, in part or in whole, to establish payment amounts for new items (71 FR 25688). We also suggested that we would make every effort to use existing fee schedule amounts or historic Medicare payment amounts for new HCPCS codes; that we would retain the method of using payment amounts for comparable items (properly calculated fee schedule amounts, or supplier price lists); but that we would discontinue the practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period. In response to our proposal, many commenters recommended a delay for finalizing regulations for the gap-filling process due to an overwhelming number of new proposals in the rule, including the

DMEPOS competitive bidding program. In our final rule published on April 10, 2007 in the **Federal Registe**r titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," we did not finalize our proposals for regulations for the gap-filling process, as a result of commenters feedback. We stated that we would address comments and regulations for the gap-filling process in future rulemaking (72 FR 17994).

In our CY 2019 ESRD PPS 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", we issued a request for information on 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 items' technologies in a way that satisfies the payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services. In the final rule, we summarized the comments received and stated we would consider these comments carefully as we contemplate future policies (83 FR 57046 through 57047). The majority of the comments focused on the aspects of transparency, sources of information, and comparable items in the gap filling process. 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. Also, some commenters did not want CMS to include 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 stated that internet and catalog prices do not reflect the costs to suppliers of compliance with the many Medicare requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation, and thereby do not contribute to a reasonable payment level. Furthermore, commenters suggested developing additional guidelines and definitions for determining whether a Medicare covered DMEPOS item is comparable to a new item 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 that would factor in the existing market demand/share/utilization of each product and price included in the array of retail prices used for gap-filling using supplier price lists. Also, the commenters expressed concern that the current gap-filling methodology does not always incorporate comparability analysis and 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.

B. Current Issues

In the CY 2020 DMEPOS proposed rule (84 FR 38373 - 38375), we discussed that

concerns have been raised by manufacturers and stakeholders about CMS' processes for establishing fees for new DMEPOS items. In particular, our process for reviewing information and data when establishing fee schedule amounts for new DMEPOS items in some instances has led to confusion among some stakeholders. For example, some manufacturers have been confused in the past about why fee schedule amounts for comparable items are sometimes used to establish fee schedule amounts for new items and how CMS determines that new items are comparable to other DMEPOS items. Some have asked for a process that is more predictable in determining the sources of data CMS would use to establish fee schedule amounts for new DMEPOS items and services, given the amount of time and money associated with investing in the development of new technology for DMEPOS items and services.

Major stakeholder concerns related to gap-filling DMEPOS fee schedule amounts have been: (1) how CMS determines that items and services are comparable; (2) sources of pricing data other than fees for comparable items; (3) timing of fee schedule calculations and use of interim fees; (4) public consultation; (5) pricing data and information integrity; and (6) adjustment of newly established fees over time.

1. Code or Item Comparability Determinations

A major stakeholder concern that we have heard frequently from manufacturers is that they do not agree that their newly developed DMEPOS item is comparable to older technology DMEPOS items and services (84 FR 38374). Our program instructions set forth a process to establish DMEPOS payment amounts following updates to HCPCS codes in section 60.3.1 of chapter 23 of the Medicare Claims Processing Manual. Under this process, using fee schedule amounts for comparable items to establish fee schedule amounts for new items can involve a number of pricing combinations including, but not limited to: (1) a one to one mapping where

the fees for one code are used to establish the fees for a new code, (2) the use of fees for a combination of codes with established fee schedule amounts; (3) the use of fees for one or more codes minus the fees for one or more other codes identifying a missing feature(s) the newer item does not include; or (4) the use of one or more codes plus additional amounts for the costs of an additional feature(s) the newer items has that the older item(s) does not include. The benefit of using fee schedule amounts for comparable items, especially items that CMS paid for during the fee schedule base period, is that average reasonable charge data or pricing data that is closer to the fee schedule base period is used in establishing the fee schedule amounts, and this better reflects the requirements of the statute than using more recent supplier prices as a proxy for reasonable charge data from the past. In addition, establishing fees for a new item that are significantly higher than fees for comparable items based on reasonable charge data can result in a competitive advantage for the new item because the suppliers of the older item are paid considerably less than the suppliers of the new item even though the new item is comparable to the older item. This could create an incentive for suppliers to furnish the new item more often than the older item, which would create an unfair advantage for the manufacturer(s) of the new item.

As explained in the CY 2020 DMEPOS proposed rule (84 FR 38374), in an effort to consider the concerns about our process for establishing payment amounts for new DMEPOS item and services, we undertook a review of the major components and attributes of DMEPOS items that we evaluate when determining whether items are comparable in order to develop and propose a standard for when and how fees for comparable items would be used to establish fees for new items. We identified five main categories upon which new DMEPOS items can be compared to older DMEPOS items: physical components; mechanical components; electrical

components (if applicable); function and intended use; and additional attributes and features.

As shown in Table 12, a comparison can be based on, but not limited to, these five main components and various attributes falling under the five main components. When examining whether an item is comparable to another item, the analysis can be based on the items as a whole or its subcomponents. A new product does not need to be comparable within each category, and there is no prioritization of the categories. The attributes listed in Table 12 under the five main components are examples of various attributes CMS evaluates within each category. We believe that establishing a framework and basis for identifying comparable items in regulation would improve the transparency and predictability of establishing fees for new DMEPOS items.

TABLE 12: Comparable Item Analysis (Any combination of, but not limited to, the categories below for a device or its subcomponents)

Components	Attributes
Physical Components	Aesthetics, Design, Customized vs. Standard, Material, Portable, Size, Temperature Range/Tolerance, Weight
Mechanical Components	Automated vs. Manual, Brittleness, Ductility, Durability, Elasticity, Fatigue, Flexibility, Hardness, Load Capacity, Flow-Control, Permeability, Strength
Electrical Components	Capacitance, Conductivity, Dielectric Constant, Frequency, Generator, Impedance, Piezoelectric, Power, Power Source, Resistance
Function and Intended Use	Function, Intended Use
Additional Attributes and Features	“Smart”, Alarms, Constraints, Device Limitations, Disposable Parts, Features, Invasive vs. Non-Invasive

We believe that by establishing a basis for comparability, stakeholders would be better informed on how these analyses are performed, creating a more transparent process that stakeholders would better understand and which would facilitate a more efficient exchange of information between stakeholders and CMS on the various DMEPOS items and services, both old and new. We believe this would also help avoid situations where comparable DMEPOS items have vastly different fee schedule amounts or where items that are not comparable have

equal fee schedule amounts.

2. Sources of Pricing Data Other Than Fees for Comparable Items

We also reviewed the concerns about our process for establishing payment amounts for new DMEPOS item and services when CMS is establishing the fee schedule amount for a new item that lacks a Medicare pricing history and CMS is unable to identify comparable items with existing fee schedule amounts (84 FR 38374). In these cases, other sources of pricing data must be used to calculate the DMEPOS fee schedule amount for the new item.

Current program instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual set forth a process for obtaining the main source of pricing data when establishing the fee schedule amount for a new item that lacks a Medicare pricing history. The instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual specify that supplier price lists may be used in these cases, and that supplier price lists can include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. In 2018, we clarified in the instructions in section 60.3 of chapter 23 of the Medicare Claims Processing Manual that potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data. Our rationale for using supplier price lists for gap-filling purposes is that supplier price lists provide the best estimate of what suppliers would have routinely charged for furnishing DMEPOS items during the fee schedule base period (if reasonable charge data for the new item is not available and comparable items with existing fee schedule amounts are not identified). When using supplier price lists to estimate what reasonable charge amounts would have been during the base period, CMS deflates the prices listed in supplier price lists to the fee schedule base period. For example, section 1834(a)(2)(B) of the Act mandates fee schedule

amounts for inexpensive DME items based on the average reasonable charges for the item(s) from July 1, 1986 through June 30, 1987. If supplier price lists are used to estimate what these average reasonable charges would have been during the base period of 1986/87, the 2018 (for example) prices listed in the supplier price lists are converted to 1986/87 dollars by multiplying the 2018 prices by a deflation factor (.439 in this example) that is listed in section 60.3 of chapter 23 of the Medicare Claims Processing Manual. The deflation factor is equal to the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the price is in effect (June of 2018 in this example) to the mid-point of the fee schedule base period (December of 1986 in this example). So, if the 2018 price is $100, this price is multiplied by .439 to compute a 1986/87 price of $43.90. CMS then applies the covered items update factors mandated by section 1834(a)(14) of the Act for use in updating the data from the base period to establish current fee schedule amounts. In the example above, the $43.90 base fee is updated to $66.80 for 2019 if the device is a class II device or $74.16 if it is a class III device, after applying the update factors mandated by section 1834(a)(14) of the Act.

In the CY 2020 DMEPOS proposed rule (84 FR 38375), we noted that another source of information is a technology assessment. We proposed that technology assessments would be used whenever we believe it is necessary to determine the relative cost of a new DMEPOS item compared to DMEPOS items that CMS paid for during the fee schedule base period. CMS would use these technology assessments to gap-fill fees for the new DMEPOS item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

As a result of our review of the major stakeholder concerns about our process for

establishing payment amounts for new DMEPOS items and services involving code or item comparability determinations, we proposed to add provisions to the regulations at §§414.110 and 414.236 to codify how CMS and our contractors will make efforts to determine when a new or existing DMEPOS item is comparable and the application of continuity of pricing when items are re-designated from one HCPCS code to another (84 FR 38375). Also as a result of our review of the major stakeholder concerns about our process for establishing payment amounts for new DMEPOS items and services without a fee schedule pricing history, we proposed to add a provision to the regulations at §§414.112 and 414.238 to establish main categories of components or attributes of DMEPOS items that would be evaluated to determine if a new item is comparable to older existing item(s) for gap-filling purposes. If it is determined that the new item is comparable to the older existing item(s), we proposed to use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. We also proposed that if it is determined that there are no comparable items to use for gap-filling purposes and other sources of pricing data must be used to calculate the DMEPOS fee schedule amount for the new item, the fee schedule amounts for a new item would generally be based on supplier or commercial price lists, deflated to the fee schedule base period and updated by the covered item update factors. If supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, we proposed to use technology assessments that determine the relative costs of the newer DMEPOS items compared to older DMEPOS item(s) to establish the fee schedule amounts for the newer DMEPOS items (84 FR 38375).

3. Timing of Fee Schedule Calculations and Interim Pricing

In some cases, HCPCS codes for new DMEPOS items may take effect before the DMEPOS fee schedule amounts have been calculated and added to the national DMEPOS fee schedule files. In these cases, the DME MACs and other contractors establish interim local fee schedule amounts in order to allow for payment of claims in accordance with fee schedule payment rules. Also, instructions for the implementation of interim fees may be released along with other updates to the national DMEPOS fee schedule files on a quarterly basis, along with any corrections of errors made in calculating fee schedule amounts (see section 60.2 of chapter 23 of the Medicare Claims Processing Manual). Changes to fee schedule amounts are generally implemented on a quarterly basis to permit preparation and testing of the fee schedule files and claims processing edits and systems.

Also, as explained in section V.B.4 of this final rule, the time period that an interim local fee may be effective for claims payment could be affected by the process used to obtain public consultation and feedback from stakeholders on the establishment of a fee schedule amount for a new item.

4. Public Consultation and Stakeholder Input

Consistent with section 531(b) of BIPA, CMS obtains public consultation on preliminary coding and payment determinations for new DME items and services each year at public meetings held at CMS headquarters in Baltimore, Maryland. These meetings are also held to obtain public consultation on preliminary coding and payment determinations for other DMEPOS items in addition to DME. The public meetings for preliminary coding and payment determinations could be used to obtain public consultation on gap-filling issues such as the comparability of new items versus older items, the relative cost of new items versus older items, and additional information on the pricing of new DMEPOS items. In addition, manufacturers of

new items often request meetings with CMS to provide information about their products, and CMS can reach out to manufacturers and other stakeholders for additional information that may be necessary in the future for pricing new DMEPOS items.

5. Pricing Data and Information Integrity

Our concerns about the integrity of the data and information submitted by manufacturers for the purpose of assisting CMS to establish new DMEPOS fee schedule amounts have led CMS to review our process for establishing fee schedule amounts for new DMEPOS items. We have concerns with using supplier invoices and information for commercial pricing such as internet and manufacturer-submitted pricing. Our experience with reviewing manufacturer submitted prices and available information on the internet for new DMEPOS has caused CMS to have the following concerns about using invoices and information for commercial pricing:

- Internet prices may not be available or reliable, especially if the posted price is the manufacturer's suggested price or some other price that does not represent prices that are actually paid in the commercial markets.
- New products are often only available from one manufacturer that controls the market and price.
- Current invoices from suppliers may not represent the entire universe of prices and typically do not reflect volume discounts, manufacturer rebates, or other discounts that reduce the actual cost of the items.
- Prices from other payers may not reflect the unique costs and program requirements applicable to Medicare payment for DMEPOS and may be excessive if they represent the manufacturer suggested retail prices rather than negotiated lower rates.

- If the prices result in excessive payment amounts, it may be difficult to determine a realistic and equitable payment amount using the inherent reasonableness authority or lower the payment amounts by, for example, including the items in a competitive bidding program
- Using excessive prices to calculate fee schedule amounts for new items would be unfair to manufacturers and suppliers of older, competitor products not priced using the same inflated commercial prices.

Numerous challenges exist including the significant number of sources of pricing information: Medicare Advantage (MA) plans, private insurers, the Veterans Benefits Administration, Tricare, Federal Employee Health Plans, Medicaid state agencies, internet prices, catalog prices, retail store prices, and other sources. Prices for a particular item or service can vary significantly depending on the source used. If the median price paid by one group of payers (for example, non-Medicare payers) is significantly higher than the median price paid by another group of payers (for example, MA plans), not using or factoring in the prices from the group of payers with the lower prices could result in grossly excessive fee schedule amounts that are then difficult to adjust using the inherent reasonableness authority, which requires numerous time consuming and resource-intensive steps. These are just a few of the reasons why we believe it is always best to use established fee schedule amounts for older items, if possible, and compare those older items to the newer items, rather than using supplier invoices and information for commercial pricing such as internet and manufacturer-submitted pricing to establish the fee schedule amounts for new items.

6. Adjustment of Fees Over Time

We have been consistent in applying the following guidelines once fee schedule amounts

have been established using the gap-filling process and included in the DMEPOS fee schedule: (1) fee schedule amounts are not changed by switching from one gap-filling method (such as using supplier price lists) to another gap-filling method (such as using fees for comparable items); and (2) fee schedule amounts are not changed as new items falling under the same HCPCS code. However, we have revised fee schedule amounts established using the gap-filling process when we determined that an error was made in the initial gap-filling of the fee schedule amounts or when adjustments were made to the fee schedule amounts based on the payments determined under the DMEPOS competitive bidding program. If fee schedule amounts were gap-filled using supplier price lists, and the prices subsequently decrease or increase, the gap-filled fee schedule amounts are not revised to reflect the changes in the prices.

However, we recognize that this gap-filling method of using supplier prices could result in excessive fee schedule amounts in cases where the market for the new category of items is not yet competitive due to a limited number of manufacturers and suppliers. We now believe that if supplier or commercial prices are used to establish fee schedule amounts for new items, and the prices decrease within 5 years (once the market for the new items is more established), that CMS should gap-fill those prices again in an effort to reflect supplier prices from a market that is more established, stable, and competitive than the market and prices for the item at the time CMS initially gap-filled the fee schedule amounts. For example, most DME items furnished during the applicable 1986/87 fee schedule base period, such as wheelchairs, hospital beds, ventilators, and oxygen equipment, were covered by Medicare in 1986/87 and paid for on a reasonable charge basis for many years (20 years in many cases). Thus the fee schedule amounts calculated using average reasonable charges from the 1986/87 fee schedule base period(s) reflected prices from stable, competitive markets. In contrast, new items that are not comparable to older items

are often made by one or a few manufacturers, so the market for a new item is not yet stable or competitive, especially as compared to the market for most DMEPOS items that have fee schedule amounts that were established based on reasonable charges during the fee schedule base period. During the various fee schedule base periods such as 1986/87 for DME, prosthetic devices, prosthetics and orthotics, most items had been on the market for many years, were made by multiple competing manufacturers, and were furnished by multiple competing suppliers in different localities throughout the nation. Therefore, the average reasonable charges from the fee schedule base period generally reflect supplier charges for furnishing items in a stable and competitive market.

We believe that if supplier or commercial prices used to gap-fill fee schedule amounts for a new item decrease within 5 years of the initial gap-filling exercise, that the new, lower prices likely represent prices from a more stable and competitive market. We also believe that supplier prices from a stable and competitive market better represent the prices in the market for DMEPOS items covered during the fee schedule base period and therefore are a better proxy for average reasonable charges from a fee schedule base period (as specified in the statute) as compared to supplier or commercial prices when an item is brand new to the market. We believe that gap-filling a second time once the market for the item has become more stable and competitive would result in fee schedule amounts that are more reflective of average reasonable charges for DMEPOS items from the fee schedule base period. We believe CMS should conduct gap-filling the second time within a relatively short period of time after the fees are initially established (5 years) and only in cases where the result of the second gap-filling is a decrease in the fee schedule amounts of less than 15 percent. Thus, if the supplier or commercial prices used to establish fee schedule amounts for a new DMEPOS item decrease by any amount below 15

percent within 5 years of establishing the initial fee schedule amounts, and fee schedule amounts calculated using the new supplier or commercial prices would be no more than 15 percent lower than the initial fee schedule amounts, we believe gap-filling should be conducted a second time to reduce the fee schedule amounts by up to 14.99 percent as a result of using new, lower prices from a more stable and competitive market. We do not believe that a similar adjustment is necessary to account for increases in supplier or commercial prices within 5 years of establishing initial fee schedule amounts since the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time.

Thus we proposed a one-time adjustment to gap-filled fee schedule amounts based on decreases in supplier or commercial prices. The statute requires CMS to establish fee schedule amounts for DMEPOS items and services based on average reasonable charges from a past period of time, generally when the market for most items was stable and competitive. In many cases, fee schedule amounts may be gap-filled using manufacturer prices or prices from other payers for new technology items that may only be made by one manufacturer with limited competition. In these situations, competition from other manufacturers or increases in the volume of items paid for by Medicare and other payers could bring down the market prices for the item within a relatively short period of time after the initial fee schedule amounts are established, creating a more stable and competitive market for the item, we believe that gap-filling using prices from a stable, competitive market is a better reflection of average reasonable charges for the item from the fee schedule base period. While the fee schedule covered item update as described in sections 1834(a)(14), 1834(h)(4), 1834(i)(1)(B), and 1842(s)(1)(B)(ii) of the Act allow for increases to the fees schedule amounts that can address increases in cost of

furnishing items and services over time or track increases in supplier or commercial prices, there is no corresponding covered item update that results in a decrease in fee schedule amounts when the market for a new item becomes more mature and competitive following the initial gap-filling of the fee schedule amounts. We also do not believe that a situation in which prices increase within a short period of time after the item comes on the market and fee schedule amounts are initially established for the item would be common. We therefore did not propose similar one-time increases in fee schedule amounts established using supplier or commercial prices, however, we invited comments on this issue.

We do not believe gap-filling fee schedule amounts for new items should be conducted a second time in situations where the prices decrease by 15 percent or more within 5 years of the initial gap-filling of the fee schedule amounts. In cases where supplier or commercial prices used to establish original gap-filled fee schedule amounts increase or decrease by 15 percent or more after the initial fee schedule amounts are established, this would generally mean that the fee schedule amounts would be grossly excessive or deficient within the meaning of section 1842(b)(8)(A)(i)(I) of the Act. In such circumstances we believe that CMS could consider making an adjustment to the fee schedule amounts in accordance with regulations at § 405.502(g). We can also consider whether changes to the regulations at § 405.502(g) should be made in the future to specifically address situations where supplier or commercial prices change by 15 percent or more and how this information could potentially be used to adjust fee schedule amounts established using supplier or commercial prices.

C. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Proposed Rule

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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 38330 through 38421), hereinafter referred to as the "CY 2020 DMEPOS proposed rule," was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019.

In the CY 2020 DMEPOS proposed rule, we proposed a gap-filling methodology for establishing payment amounts for new DMEPOS items and services and one-time adjustment to gap-filled payment amounts for DMEPOS items and services using supplier or commercial prices in cases where such prices decrease within 5 years. We solicited comments on our proposals and we summarize the comments that we received below. We received approximately 30 comments on these topics from suppliers, manufacturers, and associations or organizations representing suppliers and manufacturers. 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 DMEPOS provisions we are finalizing.

The comments and our responses to those comments are set forth below.

Comment: Some commenters expressed appreciation for the detailed explanation of the gap-filling process in the proposed rule.

Response: We appreciate the comments.

Comment: Many commenters supported increased transparency during the process for establishing fee schedule amounts for new or revised HCPCS codes that allows for stakeholder

input and consultation on the pricing methodology used as well as sources of data used in establishing the tentative or preliminary fee schedule amounts. Specifically, some commenters suggested that CMS increase transparency by establishing a process for stakeholders to receive information and provide feedback to CMS if they believe that the new HCPCS code should not be paid at the fee schedule amount that CMS is proposing as the result of the addition or subdivision of previous codes. Some commenters recommended CMS's comparability analysis should include a written report that is shared with the public, prior to a final decision on establishing new fee schedule amounts for new items. One commenter recommended simultaneous expansion of the HCPCS Level II Code application to allow applicants to address this specific topic without limiting other important information by virtue of application page limits. In addition, the commenter requested that the public meetings for DMEPOS should also be updated to allow additional presentation time for this information at the discretion of the applicant. Another commenter stated that CMS should also permit an opportunity for stakeholders to show that the pricing that was applicable in the past was established inappropriately or fails to consider technological changes.

Response: We appreciate the support for our proposal to establish a methodology for calculating fee schedule payment amounts for new DMEPOS items and services. Section 531(b) of BIPA mandated the establishment of procedures for coding and payment determinations for new DMEPOS items that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD-9-CM. We implemented procedures that permit public consultation regarding requests for codes for new DME and also extended these procedures to external requests for codes for all DMEPOS items and services. CMS holds annual public meetings to obtain public consultation on preliminary coding and payment

determinations for new DMEPOS, that is, requests for codes for DMEPOS items and services. For more information about the HCPCS public meetings, see https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html. We believe that stakeholders can use this process to provide input and consultation on sources of information for gap-filling for new DMEPOS items.

Comment: Many commenters recognized that sections of our gap-filling methodology proposal had been available in program guidance and implemented; however, the commenters did not support adding regulations which codify the program guidance. The commenters expressed concern that the methodology may not be appropriate in all situations. Also, some commenters expressed concern that the methodology maintains that the use of gap filling to address more than a 30-year span between the base year of 1986 to 1987 and 2020, which may not be a reasonable methodology to establish current year fee schedule amounts. Several commenters suggested that CMS delay implementation of the DMEPOS proposals by one calendar year to collect further stakeholder input on the appropriate cross-walk categories, comparable item methodology, and procedures.

Response: We believe that the procedures described above for obtaining public consultation on preliminary coding and payment determinations for DMEPOS can be used by stakeholders to provide consultation on sources of information for gap-filling for new DMEPOS items and other preliminary coding determinations for DMEPOS that might affect pricing of the items under the fee schedule. With regard to the comments regarding the 30-year span between the fee schedule base year of 1986 to 1987 and items furnished in 2020, sections 1834(a) and (h) of the Act specifically require that fee schedule amounts for DME, prosthetics, orthotics, and prosthetic devices be based on average reasonable charges from 1986 and 1987. Sections

1834(a)(14) and 1834(h)(4)(A) of the Act mandate annual updates to the fee schedule amounts established using average reasonable charges from 1986 and 1987, and sections 1842(b)(8) and (9) of the Act provide CMS with the authority and a process for establishing special payment amounts in cases where the fee schedule amounts become grossly excessive or deficient over time, for example, due to changes in technology. Sections 1842(b)(8) and (9) of the Act outline a process for establishing realistic and equitable payment amounts in cases where the fee schedule amounts are not inherently reasonable.

The gap-filling methodology that we proposed is a multi-step process. The proposed regulations at §§414.110 and 414.236 address the continuity of pricing when items are re-designated from one HCPCS code to another and for new items without a pricing history. The proposed regulations at §§414.112 and 414.238 set forth main categories of components or attributes of DMEPOS items that would be evaluated to determine if a new item is comparable to older existing item(s) for gap-filling purposes. The gap-filling methodology ensures a case by case review is conducted of each item that is assigned a new HCPCS code. Furthermore, as discussed in our proposal (84 FR 38373), we have repeatedly solicited feedback from our stakeholders through past rulemaking (71 FR 25687 through 25689 and 83 FR 57046 through 57047, and in our CY 2020 DMEPOS proposed rule (84 FR 38379)). Our proposed gap-filling methodology enhances predictability of pricing for new items and services and improves transparency as compared to the existing program guidance. We also believe it is important to have regulations addressing the pricing of new DMEPOS to create a firm basis for establishing fee schedule amounts in accordance with the statute. We can consider additional updates through future rulemaking if necessary.

1. Continuity of Pricing When HCPCS Codes are Divided or Combined

We proposed to add § 414.110 under subpart C for fee schedule amounts for PEN and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office, and § 414.236 under subpart D for DME, prosthetic devices, prosthetics, orthotics, surgical dressings, and therapeutic shoes and inserts to address the continuity of pricing when HCPCS codes are divided or combined. If a DMEPOS item is assigned a new HCPCS code, it does not necessarily mean that Medicare payment on a fee schedule basis has never been made for the item and service described by the new code. For example, Medicare payment on a fee schedule basis may have been made for the item under a different code. We proposed that if a new code is added, CMS or contractors would make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) would be mapped to, or cross walked to the new code(s), to ensure continuity of pricing. Since there are different kinds of coding changes, the way the proposed rule would be applied varies. For example, when the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components would not be higher than the fee schedule amount for the original item. However, when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code would continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code would be established by adding the fee schedule amounts used for the components (that is, the total of the fee schedule amounts for the components as the fee schedule amount for the global code). However, when the codes for several different items are combined

into a single code, the fee schedule amounts for the new code would be established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

We solicited comments on these proposals. The comments and our responses to the comments are set forth below.

Comment: Several commenters supported our proposal for continuity of pricing when existing HCPCS codes are divided or combined. One commenter, a national trade association for prosthetics and orthotics, stated that the use of pricing continuity when establishing new fees must be reserved only for those instances where there is a direct relationship between the former HCPCS code(s) and the new HCPCS code(s). The commenter stated failure to ensure that a continuity relationship exists could lead to fee schedule calculations that are either inadequate or excessive for the items represented by the new HCPCS codes.

Response: We thank the commenters. We agree that the use of pricing continuity when establishing new fees must be reserved only for those instances where there is a direct relationship between the former HCPCS code(s) and the new HCPCS code(s). An item must fall within the category of items described by existing codes that are combined or divided in order for the continuity of pricing rules to apply to that item. If an item does not fall under one of the four example categories, then the continuity of pricing rules would not apply. For example, if the code for a cane is divided into codes for red canes, white canes, blue canes, and canes of any color other than red, white, or blue, there is a direct relationship between the former code (cane) and the four new codes, which are all the canes that used to be described by the former code separated into new codes based on color. The direct relationship is also present in the reverse scenario where multiple canes of all different colors are combined into one code for all of the

canes that previously fell under the four separate codes. The same is true for global codes for one item versus separate codes for components of an item. If the code for a cane is divided into codes for cane handle, cane staff, and cane tip, there is a direct relationship between the three new codes for the cane handle, cane staff, and cane tip and the old code for cane since the cane handle, cane staff, and cane tip were all three previously combined in the one code for cane. The direct relationship is also present in the reverse scenario where codes for a cane handle, cane staff, and cane tip that describe the components of a cane are combined into a single code for cane.

Comment: Another concern expressed by the commenters is that the proposed continuity of pricing can lock in historical levels of reimbursement when establishing fee schedule amounts for new items. Commenters explained that if reimbursement levels are arbitrarily depressed due to the consolidation and bifurcation of codes, practitioners will have a financial incentive to provide the patient with the less expensive component in order to make ends meet. Providers should not be placed in this situation, and patients should not be denied access to the technologies with which they may achieve optimal outcomes. Therefore, the commenters urged CMS to recognize differences in separate components or devices when assigning codes, and determine reimbursement levels based on those differences so that patients can gain access to innovative DMEPOS items and services.

Some commenters stated the methodology may discourage manufacturers from innovating and investing in technology that would result in improved patient outcomes and satisfaction. Another commenter representing rehabilitation technology suppliers stated consolidating and splitting codes will have a negative effect on access to necessary technology. The commenter stated the long-term effects for individuals who rely on complex technology

requires an increase recognizing that new technology items can result in decreases in hospitalizations, pressure wounds, and other secondary health issues. Thus, the commenter suggested that CMS should instead establish more codes that have a more focused description.

Response: We do not agree. The continuity of pricing proposal addresses combining or dividing existing codes that already describe certain categories of items, for example canes. Canes are inexpensive DME items that were paid on a reasonable charge basis in 1986 and 1987. Section 1834(a)(2) of the Act mandates that the fee schedule amounts for inexpensive and routinely purchased items be based on average reasonable charges from July 1, 1986 through June 30, 1987, increased by annual covered item update factors. Thus, in accordance with the statute, the fee schedule amounts for canes are based on the 1986/87 reasonable charge data. If the code for canes is divided into four codes – one for red canes, one for white canes, one for blue canes, and one for canes of any color other than red, white, or blue, payment for the four new codes for canes would still be made on the basis of the fee schedule (and therefore the 1986/87 reasonable charge data), in accordance with the statute. If technology innovations for canes over time result in a situation where the cost of canes has risen to the point where the fee schedule amounts are grossly deficient, CMS could use the authority and process at sections 1842(b)(8) and (9) of the Act to establish a different fee schedule amount for canes than the one established in accordance with the payment rules under section 1834(a) of the Act. Subdividing the HCPCS code for a DMEPOS item such as canes into more specific items (for example, types or colors of canes) should not result in fee schedule amounts that are based on something other than the payment rules described in section 1834 of the Act.

Comment: Some commenters disagreed with CMS' concern that manufacturer suggested retail prices (MSRPs) are inflated and without merit. The commenter asserted MSRPs should be

considered when establishing base prices subject to gap-filling. One commenter recommended that CMS rescind any contractor instruction to discontinue utilizing MSRPs in the gap-filling process.

Response: We have found that manufacturer suggested retail prices are not supplier prices or commercial prices. We therefore do not believe they represent accurate pricing from actual retail markets. We do not believe that MSRPs represent a valid and reliable proxy for supplier charges or market prices for furnishing DMEPOS items. We consider fees for comparable items and verifiable supplier or commercial prices to be better proxies for supplier charges or retail costs than suggestions made by the manufacturer of the product about what the supplier or commercial prices should be for the product. As such, we will not use the MSRP to set the fee schedule rates, and instead, will rely on fees for comparable items and verifiable supplier or commercial prices in an effort to best approximate reasonable charges from the fee schedule base period for the item.

2. Establishing Fee Schedule Amounts for New HCPCS Codes for Items and Services Without a Fee Schedule Pricing History

We proposed to add § 414.112 under subpart C for fee schedule amounts for PEN and medical supplies, including splints and casts and intraocular lenses inserted in a physician's office, and § 414.238 under subpart D for DME, prosthetic devices, prosthetics, orthotics, surgical dressings, and therapeutic shoes and inserts to address the calculation of fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history. We proposed that if a HCPCS code is new and describes items and services that do not have a fee schedule pricing history, the fee schedule amounts for the new code would be established whenever possible using fees for comparable items with existing fee schedule amounts. We

proposed that items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. We proposed that if there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code would be established using supplier or commercial price lists or technology assessments if supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

We proposed that if items with existing fee schedule amounts that are comparable to the new item are not identified, the fee schedule amounts for the new item would be established using supplier or commercial price lists. However, we proposed that if the supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, we propose that the fee schedule amounts for the new item would be established using technology assessments. We proposed that supplier or commercial price lists would include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item, which could include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. We proposed that if the only available price information is from a period other than the fee schedule base period, deflation factors would be applied against current pricing in order to approximate the base period price. We proposed that the annual deflation factors would be specified in program instructions and

would be based on the percentage change in the CPI-U from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula:

((base CPI-U minus current CPI-U) divided by current CPI-U) plus one

The deflated amounts would then be considered an approximation to average reasonable charges from the fee schedule base period and would be increased by the annual covered item update factors specified in statute for use in updating average reasonable charges from the fee schedule base period, such as the covered item update factors specified for DME at section 1834(a)(14) of the Act. We proposed that, if within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts would be made using the new prices. As a result of the market for the new item becoming more established over time, the new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula. Again, supplier price lists can include catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data. We did not propose a similar adjustment if supplier or commercial prices increase by less than 15 percent, but we invited comments on this issue.

We proposed that fee schedule amounts for items and services described by new HCPCS codes without a fee schedule pricing history that are not comparable to items and services with existing fee schedule amounts may also be established using technology assessments performed by CMS and experts who could help determine the relative cost of the items and services

described by the new codes to items and services with existing fee schedule amounts. We proposed that a pricing percentage would be established based on the results of the technology assessment and would be used to establish the fee schedule amounts for the new code(s) based on the fee schedule amounts for existing codes. We proposed that technology assessments would be used when we believe it is necessary to determine the relative cost of a new item compared to items that were available during the fee schedule base period and had established fee schedule amounts. We proposed that we would use technology assessments in order to gap-fill fees for the new item when supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period.

We solicited comments on these proposals.

Comment: One commenter indicated that a separate gap-filling process is needed for orthotics and prosthetics since the cost of the professional orthotist and prosthetist services are unique to these items.

Response: We do not agree. All DMEPOS items and services will have different costs for services to furnish the item that are unique to one group of items versus another. Gap-filled fee schedule amounts for orthotics and prosthetics based on comparable orthotics and prosthetics accounts for the costs of the professional orthotist and prosthetist services because they are based on historic charges by the orthotists and prosthetists who furnished the devices in 1986/87 and therefore accounted for the cost of all of their services in the charges they submitted to Medicare during that time. Gap-filling fees for orthotics and prosthetics using supplier or commercial prices for orthotics and prosthetics likewise accounts for the costs of the professional orthotist

and prosthetist services because they are based on prices established by or paid to the orthotists and prosthetists who furnish the devices and therefore account for the cost of all of the services performed by the orthotists and prosthetists in furnishing the items.

Comment: Some commenters stated that internet and catalog prices do not reflect the costs to suppliers of compliance with the many Medicare requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation, and thereby do not contribute to a reasonable payment level. One commenter recommended that CMS apply a markup percentage to incorporate the various costs of furnishing a new DMEPOS item that are not reflected in internet or catalog prices.

Response: We thank the commenters for their input. As discussed in our CY 2020 DMEPOS proposed rule, our rationale for using supplier price lists for gap-filling purposes is that supplier price lists provide a good estimate of what suppliers would have charged for furnishing DMEPOS items during the fee schedule base period (if reasonable charge data for the new item is not available and comparable items with existing fee schedule amounts are not identified). Retail prices generally include all costs associated with furnishing items directly to the customer, including overhead and all business expenses such as licensure and accreditation, debt collection, credit cards, filing health insurance claims, delivery, set-up, and education. We believe retail prices for furnishing DMEPOS items and services are a good representation of supplier charges for furnishing DMEPOS items and services.

Comment: One commenter recommended that a weighting method should be applied to a median price when establishing a new fee schedule amount. The commenter stated that the proposed methodology does not account for relative quality, durability, clinical preference, and overall market demand for the various items falling under a HCPCS code. The commenters are

concerned that newer items within a code are given the same weight in calculating the median deflated price as items with years of history, use, and sizable market share. The commenter recommended that each item in the payment calculation be weighted based on historic market demand.

Response: We do not agree. We proposed to use supplier or commercial prices to establish fee schedule amounts for new items that we determine are not comparable to any existing item(s). Thus, we do not see the need to give certain prices more weight than other prices as long as we believe they are valid prices for the item described by the HCPCS code. We believe the proposed rule provides the flexibility for us to use the combination of supplier or commercial prices we believe best reflects what suppliers would have charged for items during the fee schedule base period.

Comment: Some commenters expressed concern with our proposals at §§ 414.112(c)(1)(i) and (ii) and §414.238(c)(1)(i) and (ii) for cases when the only available price information is from a period other than the fee schedule base period, deflation factors would be applied against current pricing in order to approximate the base period price and then the pricing amount would be increased by the annual covered item update factors specified in statute to the current year in order to establish a fee schedule amount for a new item. Several commenters expressed concerns that this step results in fee schedule amounts that are too low. Specifically, the commenters stated that CMS has omitted inflation rate factors for certain years when the statue required a freeze or no update for those years.

Response: The statute mandates that DMEPOS fee schedule amounts be based on the lesser of the actual charge for the item or the average reasonable charges from a specific period in time. As discussed previously, the statute does not describe how to determine the payment

amounts for new items for which there is no average reasonable charge data from the base period, so we have established a gap-filling methodology to attempt to calculate fee schedule amounts for new items and services that reflect the requirements under the statute. Sections 1834(a)(14)(L), 1834(h)(4)(xi), and 1842(s)(1)(B)(ii) of the Act generally require that the DMEPOS fee schedule amounts be adjusted annually by the percentage increase in the CPI–U for the 12-month period ending with June 30 of the preceding year reduced by a productivity adjustment. Through gap-filling, CMS can fill the gap in the historic reasonable charge data, apply the fee schedule update factors mandated by the Act, and then establish a fee schedule amount applicable to the year in which the item is furnished. We are finalizing §§ 414.112(c)(1)(i) and (ii) and 414.238(c)(1)(i) and (ii) as proposed.

Comment: Some commenters suggested that CMS extend the preferential treatment it has finalized for devices designated by the FDA as Breakthrough Devices applying for NTAP in the Medicare Hospital Inpatient Prospective Payment System and proposed for transitional device pass-through payments in the Hospital Outpatient Prospective Payment System to DMEPOS devices too. Specifically, if FDA has assigned "breakthrough" or "expedited access" designation to a device, clears a device under the "de novo" pathway, or decides to establish a new category for a device, then CMS should automatically determine that there is no comparable product for that new item on the DMEPOS fee schedule and set payment rates using market based pricing data accordingly.

Response: We do not agree that classification by the FDA for the purpose of approving or clearing devices as safe and effective should in any way dictate whether one device is comparable to another device for the purposes of establishing a fee schedule amount for the device. If we determine that a new DMEPOS item is comparable to an older item, we believe

that the prices established for the older item are a good estimate of what suppliers would have charged for the new item.

Comment: Some commenters suggested CMS implement an appeals process after releasing its determinations with respect to whether a new DMEPOS item is comparable to any existing item; if not, whether there is reliable market-based pricing to use in establishing a fee schedule rate; and the findings of any technology assessment performed to adjust the market-based pricing. CMS also should provide its reasoning to support each of these determinations so that the public may assess and provide feedback on that reasoning. In addition, the commenter suggested CMS should establish a timely, formal appeals process that would allow the manufacturer or other interested party to appeal the fee schedule rate based on (a) disagreement that there is a comparable product or the specific comparison that CMS made; (b) disagreement about whether CMS appropriately used (or did not use) market based pricing data; and (c) disagreement about the findings of the technology assessment.

Response: We obtain public consultation on preliminary coding and payment determinations for DMEPOS items at annual public meetings. These meetings can be used by stakeholders to provide consultation on gap-filling for new DMEPOS items and other preliminary coding determinations for DMEPOS that might affect pricing of the items under the fee schedule. Outside these meetings, the public is able to submit written documentation and other information to CMS via written correspondence at any time if they feel that the information should be considered when establishing a fee schedule amount for a DMEPOS item. CMS also meets with manufacturers and stakeholders about establishing fee schedule amounts when requested. In addition, once fee schedule amounts have been established, the public can submit written documentation and other information to CMS at any time if they believe that an error was

made in a fee schedule calculation(s) and CMS would evaluate the information and, if necessary, make corrections to the fee schedule amounts.

Comment: Many commenters opposed our proposal to apply a one-time adjustment to fee schedule amounts previously established using supplier or commercial prices to account for decreases in the supplier or commercial price within five years of establishing the initial fee schedule amounts. One commenter asserted this is not balanced for price fluctuations, and that the same price decrease policy should apply to when prices increase, and that CMS should apply the decrease/increase gap fill equitably. One commenter stated that expanding CMS' authority to reduce (but not increase) Medicare fee schedule amounts based on its perception of reduced charges through market competition is unnecessary and exceeds its statutory authority under inherent reasonableness. Also, some commenters noted since 2011, the annual Medicare fee schedule adjustment has been subject to a statutory reduction known as the Productivity Adjustment. The commenter stated that the Productivity Adjustment is intended to account for changes in economic factors which impact supplier and commercial prices.

However, some commenters supported CMS using the current inherent reasonableness process to adjust pricing—either downward or upward—if the fee schedule level for a particular DMEPOS item or service is found excessive or grossly deficient compared with supplier or commercial prices.

A few commenters stated that CMS should not presume that a short term pricing decrease is appropriate for all new HCPCS codes, and that CMS should first conduct an analysis and use statistically valid and reliable data to substantiate any reduction of up to 15 percent for a particular item. The commenters stated that statistically valid data means obtaining pricing data from at least three independent sources, and ensuring the process is transparent by disclosing

what data it proposes to use to substantiate any pricing decrease, and obtaining public input on whether the data it proposes to use to support a payment decrease is appropriate.

Response: As explained in the CY 2020 DMEPOS proposed rule, if supplier or commercial prices are used to gap-fill fee schedule amounts and these prices decrease within 5 years once the market for the new item has become more mature, we believe it would be appropriate to make a one-time adjustment to the fee schedule amounts as long as the same pricing sources are used and the new prices are not lower than the initial prices by 15 percent or more. CMS has been using supplier or commercial prices to gap-fill fee schedule amounts for DMEPOS items since 1989 and this method of gap-filling has not resulted in barriers to access for these items and services. If the prices decrease over time, we believe they would still be valid and reliable market-based prices representing what suppliers charge for furnishing the items and services. As discussed in our proposal (84 FR 38377), we do not believe that a similar adjustment is necessary to account for increases in supplier or commercial prices within 5 years of establishing initial fee schedule amounts since the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time. We do not agree that the productivity adjustment would fully address more than very modest decreases in prices as the average adjustment over the past 5 years from 2015 to 2019 has been only 0.5 percent.

Comment: CMS received comments that emphasized concern for the proposed five framework comparison categories in our proposal (84 FR 38374 through 38375) to determine if an item in a new HCPCS code is comparable to items in an existing HCPCS code. Those categories are physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. Commenters stated additional criteria

should be added to the comparability (for example, service intensity of the item, value to patient care, professional services, customization, intended population, health economic, digital technologies, service intensity, clinical outcome, and clinical care) and the focus of each criterion should be weighted. However, many commenters stated that in order to be considered comparable an item should be interchangeable. Some expressed concern that CMS and/or contractors do not have the required expertise to understand and evaluate technology's inherent relative complexities and costs. That manufacturers, stakeholders, and beneficiaries should have a say in final pricing. On the other side, CMS received comments that supported the transparency of the five categories of used to determine comparability and support of not having a weighted prioritization.

Response: We appreciate the input from the commenters on the proposed five framework comparison categories for determining whether a new item is comparable to items with existing fee schedule amounts. We believe the five categories capture the main categories that should be considered. We would compare all attributes and features that impact the cost of the items, such as service intensity of the item and all services associated with furnishing the item, customization of the item, intended population or intended use, and digital technologies. An evaluation and comparison of attributes that do not impact a supplier's cost for furnishing an item, such as value to patient care, would likely not be necessary in determining whether items are comparable for pricing purposes.

Comment: Many commenters expressed concerns about the use of technology assessments for use in establishing fee schedule amounts for new DMEPOS items. The commenters stated that our proposal (84 FR 38374 through 38375) lacked sufficient details on how the technology assessment process would work and what impact it might have on payment

for DMEPOS items and services. The commenters stated a technology assessment is a complicated process and requires the expertise of engineers and others to understand technology's inherent relative complexities and costs. The commenters asserted that even a third party would not be able to break down the costs of a device to understand its production and related costs. Some commenters stated that technology assessments would fail to account for changes in manufacturing (for example, direct and indirect labor, material and equipment, taxes, and shipping costs).

Response: We appreciate the feedback from our stakeholders and we are not finalizing §§ 414.110(d) and 414.238(d) in order to have the opportunity to consider additional information on the use of technology assessments in the gap-filling methodology for DMEPOS items and services. We will consider whether to include a revised proposal addressing the use of technology assessments in gap-filling in future rulemaking. Even so, if supplier prices are not available, we would not use a manufacturer's suggested price for their own product to gap-fill the fees. We would use information from the comparability analysis and any other pricing information that is available to establish the fee schedule amount so that it best reflects what the 1986/87 supplier charges for the item would have been if the item were on the market during the fee schedule base period.

Final Rule Action: After consideration of comments received on the CY 2020 DMEPOS proposed rule and for the reasons we set forth previously in this final rule, we are finalizing §§414.110 and 414.236 as proposed. In addition, we are finalizing §§414.112 and 414.238 as proposed, with the exceptions of §§414.112(d) and 414.238(d), which outlined a process for using technology assessments to establish the fee schedule amounts for new DMEPOS items.

VI. Standard Elements for a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order; Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

A. Background

The Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Improper Payments Information Act of 2002 (IPIA) (Pub. L. 107-300), as amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA) (Pub. L. 111–204), as updated by the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (Pub. L. 112-248). As stated in the CERT 2018 Medicare FFS Supplemental Improper Payment Data report, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims had an improper payment rate of 35.5 percent, accounting for approximately 8.2 percent of the overall Medicare FFS improper payment rate.[43]

The Department of Health and Human Services Office of Inspector General (HHS-OIG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness in the programs and operations of the HHS. HHS-OIG's mission is to protect the integrity of HHS programs and is carried out through a network of audits, investigations, and inspections.

The Government Accountability Office (GAO) audits the Centers for Medicare & Medicaid Services' (CMS') operations to determine whether federal funds are being spent

[43]2018 Medicare Fee-for-Service Supplemental Improper Payment Data: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/2018MedicareFFSSupplementalImproperPaymentData.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending. Accessed September 4, 2019.

efficiently and effectively, as well as to identify areas where Medicare and other CMS programs may be vulnerable to fraud and/or improper payments.

A number of HHS-OIG and GAO reports have focused on waste, fraud, and abuse within the DMEPOS sector. In an effort to reduce improper payments, CMS has issued regulations and sub-regulatory guidance to clarify the payment rules for Medicare DMEPOS suppliers rendering items and submitting claims for payment.

Currently, the scope of payment for medical supplies, appliances, and devices, including prosthetics and orthotics, are defined at 42 CFR 410.36(a) and the scope and certain conditions for payment of durable medical equipment (DME) are described at § 410.38. Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. These conditions of payment vary by item, but are specified in statute and in our regulations. They are further detailed in our manuals and in local and national coverage determinations.

The purpose of this rule is to simplify and revise conditions of payment aimed at reducing unnecessary utilization and aberrant billing for items described in § 410.36(a) and § 410.38. To avoid differing conditions of payment for different items paid under the DMEPOS Fee Schedule, we proposed the conditions of payment described in proposed § 410.38(d), would also be applied to items specified under § 410.36(a).

1. Face-to-Face and Prescription Requirements for Power Mobility Devices (PMDs)

Section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), in part, added conditions of coverage specific to power mobility devices (PMDs) in section 1834(a)(1)(E)(iv) of the Social Security Act (the Act), that

specify payment may not be made for a covered item consisting of a motorized or power wheelchair unless a physician (as defined in section 1861(r)(1) of the Act), physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) (as such non-physician practitioners are defined in section 1861(aa)(5) of the Act) has conducted a face-to-face examination of the individual and written a prescription for the item.

On April 5, 2006, we published a final rule in the **Federal Register** titled "Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles" (71 FR 17021), hereinafter referred to as "April 2006 final rule," to implement the requirements for a face-to-face examination and written prescription in accordance with the authorizing legislation. In § 410.38(c)(2)(ii), we required that prescriptions for PMDs must be in writing, signed and dated by the treating practitioner who performed the face-to-face examination, and received by the supplier within 45 days after the face-to-face examination. The April 2006 final rule mandated that the supplier receive supporting documentation, including pertinent parts of the beneficiary's medical record to support the medical necessity for the PMD, within 45 days after the face-to-face examination. It provided that the PMD prescription must include a 7-element order composed of—(1) the beneficiary's name; (2) the date of the face-to-face examination; (3) the diagnoses and conditions that the PMD is expected to modify; (4) a description of the item (for example, a narrative description of the specific type of PMD; (5) the length of need; (6) the physician or treating practitioner's signature; and (7) the date the prescription is written.

2. Face-to-Face and Prescription Requirements for Specified DMEPOS

Section 6407 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) amended section 1834(a)(11)(B) of the Act, which already required a written order, to also

require that a physician, PA, NP, or CNS have a face-to-face encounter with the beneficiary within a 6-month period preceding the written order for certain DMEPOS, or other reasonable timeframe as determined by the Secretary of the Department of Health and Human Services (the Secretary).

On November 16, 2012, we published a final rule with comment period in the **Federal Register** titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013" (77 FR 68892) hereinafter referred to as "November 2012 final rule," that established a list of DME items subject to the face-to-face encounter and written order prior to delivery requirements as a condition of payment. CMS selected items for this initial list based on an item having met one of the following four criteria: (1) items that required a written order prior to delivery per instructions in the Medicare Program Integrity Manual (at the time of rulemaking); (2) items that cost more than $1,000 (at the time of rulemaking in 2012); (3) items CMS, based on experience and recommendations from the DME MACs, believed were particularly susceptible to fraud, waste, and abuse; and (4) items determined by CMS as vulnerable to fraud, waste and abuse based on reports of the OIG, GAO, or other oversight entities.

Section 504 of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) amended section 1834(a)(11)(B)(ii) of the Act to eliminate the requirement that only physicians could document face-to-face encounters, including those conducted by NPs, PAs, or CNSs. In effect, this change in the law permits NPs, PAs, or CNSs to document their face-to-face encounter, without the co-signature of a physician. For the purpose of this rule, we use the term "practitioner" as an all-inclusive term

to capture physicians and non-physician practitioners (that is, NPs, PAs, and CNSs).

Section 1834(a)(11)(B)(ii) of the Act, as amended by section 504 of MACRA, mandates that the Secretary require for certain items of DMEPOS (as identified by the Secretary) a written order pursuant to a physician, a PA, an NP, or a CNS (as these three terms are defined in section 1861 of the Act) documenting that such a physician, PA, NP, or CNS has had a face-to-face encounter (including through use of telehealth under section 1834 (m) of the Act and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

Prior to this rule, the regulation at § 410.38(g)(4) required written orders for certain specified covered items, as selected per the regulatory instruction in § 410.38(g)(2), to contain 5 elements: (1) the beneficiary's name; (2) the item of DME ordered; (3) the signature of the prescribing practitioner; (4) the prescribing practitioner National Provider Identifier (NPI); and (5) the date of the order.

3. Subregulatory Requirements for Orders and Face-to-Face Encounters for Other DMEPOS

CMS through subregulatory guidance developed standards for orders for DMEPOS items not included on the list of specified covered items requiring a written order prior to delivery and a face-to-face encounter. In addition, certain items of DMEPOS require face-to-face encounters in item-specific coverage requirements, such as those in the MAC-developed local coverage determinations.

4. Prior Authorization

The Medicare Prior Authorization of PMDs Demonstration was initially implemented in 2012 in 7 states and subsequently extended in 2014 to 12 additional states (for 19 states in total)

until its completion in August of 2018. For additional information about this demonstration, see the notice we published in the **Federal Register** on August 3, 2012 (77 FR 46439).

Based on early signs of the demonstration's promising results, on December 30, 2015 we published a final rule in the **Federal Register** titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (80 FR 81674), hereinafter referred to as the "December 2015 final rule," that established a permanent prior authorization program nationally. The December 2015 final rule was based on the authority outlined in section 1834(a)(15) of the Act, which permits the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Specifically, the December 2015 final rule established a new provision at § 414.234 that specified a process for the prior authorization of DMEPOS items. The provision interpreted "frequently subject to unnecessary utilization" to include items on the DMEPOS fee schedule with an average purchase fee of $1,000 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U)) or greater, or an average rental fee schedule of $100 (adjusted annually for inflation using CPI-U) or greater, that also met one of the following two criteria: (1) the item has been identified as having a high rate of fraud or unnecessary utilization in a report that is national in scope from 2007 or later, as published by the OIG or the GAO; or (2) the item was listed in the 2011 or later CERT program's Annual Medicare FFS Improper Payment Rate DME and/or DMEPOS Service Specific Report(s). In addition, § 414.234(b) lists DMEPOS items that met these criteria on a "Master List of Items Frequently Subject to Unnecessary Utilization." Placement on the Master List makes an item eligible for CMS to require prior authorization as a condition of payment. That regulation

instructed CMS to select items from the Master List to require prior authorization as a condition of payment and to publish notice of such items in the **Federal Register**. We stated that items on the Master List would be updated annually, based on payment thresholds and changes in vulnerability reports, as well as other factors described in § 414.234.

We noted in the proposed rule (84 FR 38380) that burden estimates associated with prior authorization are related to the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the contractor for medical review. Prior authorization does not change documentation requirements specified in policy or who originates the documentation. The associated information collection (OMB Control number 0938-1293) was revised and OMB approved the revision on March 6, 2019.

5. Overview

Over time, the implementation of the aforementioned overlapping rules and guidance may have created unintended confusion for some providers and suppliers and contributed to unintended noncompliance. We continue to believe that practitioner involvement in the DMEPOS ordering process, through the face-to-face and written order requirements, assists in limiting waste, fraud, and abuse. We believe practitioner involvement also helps to ensure that beneficiaries can access DMEPOS items to meet their specific needs. In addition, we maintain that the explicit identification of information to be included in a written order/prescription, for payment purposes, promotes uniformity among practitioners and precision in rendering intended items. It also supports our program integrity goals of limiting improper payments and fraudulent or abusive activities by having documentation of practitioner oversight and standardized ordering requirements. Likewise, prior authorization supports ongoing efforts to safeguard beneficiaries'

access to medically necessary items and services, while reducing improper Medicare billing and payments. This is important because documentation of practitioner involvement, including their orders for DMEPOS items and documented medical necessity (as assessed under prior authorization), are all used to support proper Medicare payment for DMEPOS items.

This final rule streamlines the existing requirements and reduces provider or supplier confusion, while maintaining the concepts of practitioner involvement, order requirements, and a prior authorization process. We believe streamlining our requirements furthers our efforts to reduce waste, fraud, and abuse by promoting a better understanding of our conditions of payment, which may result in increased compliance.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Proposed Rule

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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 38330 through 38421), hereinafter referred to as the "CY 2020 DMEPOS proposed rule," was published in the **Federal Register** on August 6, 2019, with a comment period that ended on September 27, 2019. In that rule, we proposed technical corrections; updates to definitions and documentation requirements; standard elements of a DMEPOS order; the creation of and inclusion factors for the "Required Face-to-Face Encounter and Written Order Prior to Delivery List"; and authority

to suspend face-to-face encounter and written order prior to delivery requirements at § 410.38. In addition, we proposed to establish a "Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements" (the "Master List"); revisions to the factors for placing an item on the Required Prior Authorization List; and the authority to exempt compliant suppliers at § 414.234. We received approximately 29 public comments on our proposals, including comments from suppliers, practitioners, professional supplier organizations, electronic record vendors, beneficiary advocacy organizations and health care systems.

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.

1. Technical Corrections to § 410.38(a) and (b).

We proposed to make technical changes to § 410.38 by adding headings for paragraphs (a) and (b), and to update obsolete language under paragraph (a). For paragraphs (a) and (b), we proposed the headings as "General scope" and "Institutions that may not qualify as the patient's home," respectively. Paragraph (a) addresses the general scope of the DME benefit, but includes outdated language related to the Medicare payment rules for DME, which are more appropriately addressed under §§ 414.210 and 414.408. In addition, the terms "iron lungs" and "oxygen tents" refer to obsolete DME technology that is no longer in use. We therefore proposed to revise § 410.38(a) to remove language related to payment rules for DME and to replace the terms "iron lungs" and "oxygen tents" with "ventilators" and "oxygen equipment," respectively.

We received comments on the technical corrections to § 410.38(a) and (b), and our responses are below.

Comment: Some commenters supported CMS' proposal to modernize regulations through the removal of outdated language related to the Medicare payment rules for DME, including the terms "iron lungs" and "oxygen tents."

Response: We appreciate the commenters support of our proposal.

Final Rule Action: We are finalizing the changes to § 410.38 by adding headings for paragraphs (a) and (b), and by updating obsolete language in paragraph (a).

2. Definitions

We proposed to update § 410.38(c) to include definitions related to certain requirements for the DMEPOS benefit.

We proposed to add new definitions, redesignate existing definitions within the regulatory text, and amend existing definitions. We shared our belief that these changes would promote transparency and create uniform definitions applicable across the DMEPOS benefit and consequently, increase understanding of DMEPOS payment requirements, and may result in increased compliance.

We proposed at § 410.38(c) to include the following terms:

- Physician means a practitioner defined in section 1861(r)(1) of the Act. We proposed this definition as paragraph (c)(1) and we noted that it is the same as our current definition of "physician" in § 410.38.
- Treating practitioner means both physicians, as defined in section 1861(r)(1) of the Act, and non-physician practitioners (that is, PAs, NPs, and CNSs) defined in section 1861(aa)(5) of the Act. This definition is consistent with the practitioners permitted to perform and document the face-to-face encounter pursuant to section 1834(a)(11)(B) of the Act. We proposed this definition as paragraph (c)(2).

- We proposed that a DMEPOS supplier means an entity with a valid Medicare supplier number that furnishes durable medical equipment prosthetics orthotics and/or supplies including an entity that furnishes these items through the mail. We proposed this definition as paragraph (c)(3).
- We proposed that a written order/prescription means an order/prescription that is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS. We proposed that all DMEPOS items require a written order/prescription to be communicated to the supplier prior to claim submission. In the case of items appearing on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we proposed that the written order/prescription must additionally be communicated to the supplier before the delivery of the item. As discussed further below, we also noted our intent to standardize the elements of written orders/prescriptions provided for DMEPOS. We proposed this definition as paragraph (c)(4).
- We proposed that a face-to-face encounter means an in-person or telehealth encounter between the treating practitioner and the beneficiary. As discussed further below, we also noted our intent that the face-to-face encounter be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered. We also noted our intent to standardize the face-to-face and documentation requirements for certain DMEPOS. We proposed this definition as paragraph (c)(5).
- We proposed to maintain the definition of a Power Mobility Device (PMD), which is a covered item of DME that is in a class of wheelchairs that includes a power wheelchair (a

four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home. Section 410.38(c)(1) required reformatting to accommodate the proposed unified conditions of payment and therefore, we proposed this definition as paragraph (c)(6).

- We proposed that the Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, referred to as the "Master List," means items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list were specified in proposed § 414.234(b). We stated the Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List. We proposed this definition as paragraph (c)(7).
- We proposed that the Required Face-to-Face Encounter and Written Order Prior to Delivery List means a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery, and communicated to the public via a 60-day **Federal Register** notice. When selecting items from the Master List for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we proposed that CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis (for example, comparing the cost of review versus the anticipated amount of improper payment identified), emerging trends (for example, billing patterns, medical review findings,) vulnerabilities identified

in official agency reports, or other analysis. We proposed this definition as paragraph (c)(8). We noted that the Required Face-to-Face Encounter and Written Order Prior to Delivery List is distinct from the "Required Prior Authorization List."

We received comments regarding our proposal to update § 410.38(c) to include definitions related to certain requirements for the DMEPOS benefit. The comments and our responses are set forth below.

Comment: Some commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. Various commenters suggested we increase the notification period to more than 60 days.

Response: We agree that in some cases, a longer notification timeframe may be appropriate. For example, if we choose to require prior authorization for an item that is very similar to an item already subject to prior authorization, we may choose a shorter notice period, while we may choose a longer period for items that require more substantial education and changes in practice to put into operation. We believe similar types of considerations are appropriate in relation to the face-to-face encounter and written order prior to delivery requirements. Therefore, we are revising the public notice process to allow for longer notification timeframes so that Required Face-to-Face Encounter and Written Order Prior to Delivery List would become effective no less than 60 days after a **Federal Register** notice publication and CMS website posting.

Final Rule Action: We are revising the 60-day public notice timeframe listed in the Required Face-to-Face Encounter and Written Order Prior to Delivery List definition to state "The list of items is published in the Federal Register and posted on the CMS website. The list is effective no less than 60 days following its publication." All other definitions will be finalized

as proposed.

3. Master List

a. Creating the Master List

In the April 2006 final rule, we established face-to-face examination and written order prior to delivery requirements for PMDs.

In the November 2012 final rule (77 FR 68892), we created a list of Specified Covered Items always subject to face-to-face encounter and written order prior to delivery requirements based on separate inclusion criteria outlined in § 410.38.

In the December 2015 final rule (80 FR 81674), we created a "Master List of Items Frequently Subject to Unnecessary Utilization" based on inclusion criteria found at § 414.234 that would potentially be subject to prior authorization upon selection. In the CY 2020 DMEPOS proposed rule, we proposed to create one list of items known as the "Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements," or the "Master List," and specified the criteria for this list in § 414.234.

In the CY 2020 DMEPOS proposed rule, we shared our belief that our proposed changes would harmonize the resultant three lists created by the former rules and develop one master list of items potentially subject to prior authorization and/or the face-to-face encounter and written order prior to delivery requirement. We further explained, in determining DMEPOS appropriate for inclusion in the Master List, our belief that there are inherent similarities in those items posing vulnerabilities mitigated by additional practitioner oversight (face-to-face encounters and written orders prior to delivery) and those items posing vulnerabilities mitigated by prior authorization. Therefore, we proposed that the Master List would include both those items that

may potentially be subject to the face-to-face encounter and written order prior to delivery requirements as conditions of payment upon selection, and those items that may potentially be subject to prior authorization as a condition of payment upon selection. (See Table 13: Master List Of DMEPOS Items Potentially Subject to a Face-To-Face Encounter and Written Order Prior To Delivery and/or Prior Authorization Requirements.) We noted that prosthetic devices and orthotic and prosthetic items have the same requirements under section 1834(a)(11) of the Act as other items of DME have in statute. Section 1834(h)(3) of the Act requires that section 1834(a)(11) of the Act apply to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of DME. Therefore, we proposed the items identified in § 410.36(a) would be subject to the requirements identified in proposed § 410.38.

While the regulatory requirements used to create the resultant three lists (outlined in the April 2006, November 2012, and December 2015 final rules) were inherently distinct and conformed to different statutory mandates, we nonetheless assessed the items captured by those individual lists to determine whether the items are included in the new proposed inclusion criteria and resultant Master List. We compared the proposed Master List to both those items of DME that require a face-to-face encounter and written order prior to delivery due to (i) the statutory requirements for all PMDs or (ii) the list of specified covered items of DME that was established in accordance with section 1834(a)(11)(B) of the Act and the November 2012 final rule. We found that 103 items currently captured as either a PMD or included in the list published in the November 2012 rule would not be included in the proposed Master List. We further identified that there are 306 items potentially subject to a face-to-face encounter and a written order prior to delivery under the proposed Master List that did not require it under the conditions of payment that preceded this regulation. The remainder of items on the proposed

Master List were both subject to a face-to-face encounter and a written order prior to delivery under the conditions of payment that preceded this regulation, and are potentially subject to these conditions of payment per this final rule. All 135 items that were potentially subject to prior authorization under the conditions of payment that preceded this regulation are also included in our proposed Master List. We outlined the inclusion criteria that developed the proposed Master List of 413 items potentially subject to these conditions of payment.

We shared that while the Master List created by the CY 2020 DMEPOS proposed rule (84 FR 38382) would increase the number of DMEPOS items potentially eligible to be selected and added to the Required Prior Authorization list (which requires a technical update to Paperwork Reduction Act Information Collection CMS-10524; OMB-0938-1293,) there is no newly identified burden, no change in the required documentation associated with prior authorization and no plans to exponentially increase the number of items subject to required prior authorization in the near future.

We proposed at § 414.234(b)(1) that items that meet the following criteria would be added to the Master List:

- Any DMEPOS items included in the DMEPOS fee schedule that have an average purchase fee of $500 (adjusted annually for inflation using CPI-U, and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of $50 (adjusted annually for inflation using CPI-U, and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable

FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a recent 12-month period, that are:

++ Identified as having a high rate of potential fraud or unnecessary utilization in an OIG or GAO report that is national in scope and published in 2015 or later, or

++ Listed in the CERT 2018 or later Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate.

- The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

++ double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

++ exceeding a 30 percent increase in payments for the item from the preceding 12-month period.

- Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

We provided the following hypothetical data patterns, which are not factual, to demonstrate how data would be assessed in coordination with our new criteria for identifying items, subject to aberrant billing patterns and having a lack of explanatory contributing factors, that would be appropriate for inclusion in the Master List:

Example 1: After removing any item for which there are less than 1,000 claims billed or less than $1 million paid from CY 2018, there were $6.2 billion in total payments for all DMEPOS items. There were $5.6 billion in total payments for all DMEPOS items in the prior 12-month period (CY 2017). The percent change in payments between CY 2017 and CY 2018 is 10.7 percent. The doubled percent change is 21.4 percent.

- DMEPOS Item X had $3.2 million in payments in CY 2018 and $2.4 million in payments in CY 2017. This is a 33.3 percent change in payment for DMEPOS Item X. Therefore, Item X would be added to the Master List since it exceeds a 30 percent increase in payments, which is greater than double the percent change of all DMEPOS claim payments, for items that meet the claim and payment criteria (more than 1,000 claims billed or $1 million paid), from the preceding 12-month period.
- DMEPOS Item Y had $17.1 million in payments in CY 2018 and $13.4 million in payments in CY 2017. This is a 27.6 percent change in payment for DMEPOS Item Y. Therefore, Item Y would not be added to the Master List since it is less than 30 percent.

Example 2: After removing any item for which there are less than 1,000 claims billed or less than $1 million paid from CY 2018, there were $6.5 billion in total payments for all DMEPOS items. There were $5.5 billion in total payments for all DMEPOS items in the prior 12-month period (CY 2017). The percent change in payments between CY 2017 and CY 2018 is 18.2 percent. The doubled percent change is 36.4 percent.

- DMEPOS Item X had $20.4 million in payments in CY 2018 and $14.3 million in payments in CY 2017. This is a 42.7 percent change in payment for DMEPOS Item X. Therefore, Item X would be added to the Master List since it exceeds a 36.4 percent increase in payments which is more than double the percent change in payment in the preceding 12-month

period, and is greater than 30 percent.

- DMEPOS Item Y had $3.2 million in payments in CY 2018 and $2.4 million in payments in CY 2017. This is a 33.3 percent change in payment for DMEPOS Item Y. Therefore, Item Y does not meet the inclusion criteria since it is less than 36.4 percent or double the percent change in payment in the preceding 12-month period.

The proposed criteria adheres to the statutory language in section 1834(a)(11)(B) of the Act, which allows us to specify covered items for the face-to-face and written order prior to delivery requirements, and section 1834(a)(15) of the Act, which provides discretion for the Secretary to develop and periodically update a list of items that on the basis of prior payment experience, are frequently subject to unnecessary utilization.

We noted that under our proposal, any item that by statute requires a face-to-face encounter, a written order prior to delivery, or prior authorization would be added to the Master List and potentially subject to any of these requirements. For example, in accordance with section 1834(a)(1)(E)(iv) of the Act, payment may not be made for motorized or power wheelchairs unless there is a face-to-face encounter and a written order prior to delivery. We stated that motorized and power wheelchairs would therefore also potentially be subject to the prior authorization requirement. We shared our belief that this is appropriate because any item statutorily subject to additional program integrity measures can reasonably be assumed to be "frequently subject to unnecessary utilization" (the standard for prior authorization in section 1834(a)(15)) and therefore should be included on the Master List.

In addition, we expressed that proposing criteria based on (1) cost, (2) spending thresholds, and (3) data conveying possible overutilization and/or abuse allows us to more effectively focus our program integrity efforts. While the November 2012 and December 2015

final rules included higher cost thresholds ($1,000 purchase/$100 rental thresholds), we noted that programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items, which is the reason we proposed to lower these cost thresholds. We proposed the $500 purchase/$50 rental thresholds based on analysis of the current fee schedule cost of DMEPOS items when compared with known vulnerabilities. This threshold captures items of known vulnerability, as previously identified and included in the Master List of items potentially subject to prior authorization, while remaining cognizant of the overall impact to DMEPOS items. To select the cumulative threshold, we identified low cost items with a significant cumulative impact on the Trust Fund. We then found that approximately the top 10 items individually account for at least 1.5 percent of DMEPOS allowed costs. We accordingly proposed 1.5 percent to capture the items with the highest allowed amounts, while not creating an overly inclusive list. However, we recognized that item(s) may fail to meet the $500 purchase, $50 rental, or cumulative cost thresholds identified in the CY 2020 DMEPOS proposed rule (84 FR 38383); nonetheless, such items may demonstrate aberrant billing patterns inconsistent with predictable claim volumes.

We proposed to use the CERT Medicare FFS Supplemental Improper Payment Data to identify DMEPOS service-specific rates of improper payments; and the OIG and GAO reports to identify DMEPOS items as having a high rate of fraud or unnecessary utilization. Inclusion of an item in these reports are indications that the item is frequently subject to unnecessary utilization. We recognize that there are inherent delays from the time aberrant billing patterns are identified and the publication of CERT, OIG, and GAO reports. Under our prior regulations, we captured reports dating as far back as 2007; however, we have learned that billing practices may be subject to imminent shifts as a result of changed policies from CMS, new technologies

and other emerging trends.

Our objective is to focus on more current data, and in the CY 2020 DMEPOS proposed rule (84 FR 38383), we redefined the timeframe for identifying items in OIG and GAO reports to 2015 or later, in CERT Medicare FFS Supplemental Improper Payment Data reports to 2018 or later, and added a new Master List inclusion criteria to capture current aberrant billing patterns. We believe the Master List is a good representation of those items that may pose risk to the Medicare Trust Funds. In future years, we would apply the new criteria on billing patterns occurring over a 12-month period to allow CMS to be nimble to industry change.

We proposed the identification of aberrant billing patterns to be limited to those instances in which the total payment is at least 1 million dollars and at least 1,000 claims in a recent 12-month period prior to CMS updating the list annually. This avoids us targeting items with very low payments or very few claims, when considered overall.

We summarize the comments and our responses for the Master List section of this final rule along with our final decisions applicable to this section.

Comment: Several commenters were supportive of CMS' proposal to harmonize the three lists through the creation of one Master List. However, some commenters expressed concern that the extended length of the list was indicative of our intent to prior authorize more frequently, and worried about delays in patient care.

Response: The longer Master List grants the agency the ability to impose conditions of payment to mitigate emerging program integrity vulnerabilities for a wider array of items, but is not indicative of any known plans to widely increase prior authorization. Rather, items would only be moved to the Required Prior Authorization List after consideration of the regulatory

factors—including item utilization, cost, and other analyses—and would be subject to a no less than a 60-day notice.

We encourage open communication between the beneficiaries and the practitioners, as well as between practitioners and suppliers to ensure that beneficiaries receive medically necessary items in a timely fashion. If beneficiaries, practitioners, or suppliers are observing or experiencing significant delays in beneficiary access to DMEPOS items, they are advised to call 1-800-MEDICARE to report their specific concerns. We note that this rule requires CMS to consider multiple factors prior to subjecting DMEPOS items to conditions of payment, and grants CMS the authority to suspend such condition of payment or remove DMEPOS items from the required list, as needed.

Comment: Some commenters suggested CMS retain the prior cost thresholds ($1000 purchase price/ $100 rental price) for inclusion on the Master List.

Response: We noted in the preamble that the November 2012 and December 2015 final rules included higher cost thresholds ($1,000 purchase/$100 rental thresholds). Programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items, which is the reason we proposed to lower these cost thresholds. We considered known vulnerabilities impacting DMEPOS items, and the item costs listed on the DMEPOS fee schedule prior to selecting the $500 purchase/$50 rental thresholds.

Comment: Some commenters questioned the methodology for inclusion on the list and requested greater transparency in identifying how an item was selected for inclusion. For example, some commenters suggested that CMS increase its percentage threshold for identifying an item's Medicare expenditures, in relation to Medicare expenditures for all DMEPOS items over a recent 12-month period, from 1.5 percent to 2.0 percent. Commenters also questioned the

inclusion of certain HCPCS codes on the list. For example, a commenter questioned which criteria applied to HCPCS code A4351- intermittent urinary catheter.

Response: While we appreciate stakeholder feedback on the inclusion criteria, we are not adopting changes at this time. The criteria were based on analysis of our data and consideration of known vulnerabilities and burden. We continue to believe the proposed criteria are most appropriate. While items may meet multiple factors for inclusion, items are only added to the list if they meet one of the inclusion criteria. Due to the varying inclusion criteria, the potential for items to meet multiple factors, and the ever evolving nature of the list, we do not believe it's feasible to maintain a current list that also identifies our underlying reason for inclusion on the list.

We have confirmed the appropriateness of including the HCPCS on the Master List, including those questioned by commenters, based on the list inclusion criteria. For example, commenters questioned the inclusion of HCPCS A4351-intermittent urinary catheter on the Master List. Urological supplies appears on the 2018 CERT Medicare FFS Supplemental Improper Payment Data report chart titled "Top 20 Service Types with Highest Improper Payments: DMEPOS." Thus, HCPCS A4351 meets the Master List inclusion criteria both based on cost (1.5 percent of DMEPOS fee schedule expenditure) and based on its identification in a CERT Medicare FFS Supplemental Improper Payment Data report as an item subject to high improper payments.

Comment: One commenter suggested that the application of the face-to-face encounter and written order prior to delivery was inappropriate for prosthetics and orthotics, and therefore, it is inappropriate to create a combined Master List. For example, commenters suggested that

many of the Master List codes describe orthoses that typically must be provided to treat an acute injury.

Response: We respectfully disagree that the application of the face-to-face encounter and written order prior to delivery is inappropriate for prosthetics and orthotics. In our proposal, we noted that prosthetic devices and orthotic and prosthetic items have the same requirements under section 1834(a)(11) of the Act as other items of DME have in statute, and therefore we believe their inclusion to be appropriate. Further practitioners typically have face-to-face encounters in order to assess beneficiary's acute injury before ordering the appropriate orthoses. Therefore, we believe the documentation resulting from this face to face encounter does not create any barrier to treating acute injuries.

Comment: One commenter expressed concern that the lowered cost threshold would create undue burden, because it expands the list to include less expensive DMEPOS items and therefore less likely to achieve savings.

Response: We agree with the commenter that a successful program balances both the cost of the item and resources extended to maintain program integrity. However, experience with prior authorization has demonstrated methods of program efficiencies that allow us to look at lower cost items and still be cost effective.

Comment: One commenter stated that the creation of a single master list of HCPCS codes subject to multiple CMS conditions of payment will further confuse providers and beneficiaries.

Response: We believe there are inherent similarities in those items posing vulnerabilities that can be mitigated by additional practitioner oversight (face-to-face encounters and written orders prior to delivery) and those items posing vulnerabilities that can be mitigated

by prior authorization. We emphasize that we will maintain separate "required" lists that will enable us to select the most appropriate program integrity action. We believe that the dissemination of two separate lists derived from the Master List will decrease provider burden and confusion.

Comment: One commenter suggested that CMS recognize that while some increases in utilization are indicative of abusive behaviors, others are a result of recent innovations and may be appropriate.

Response: While our rule allows us to focus on increased utilization, we specifically note that we would consider contributory factors when selecting items posing vulnerabilities that may be appropriate for application of these conditions of payment. An example of a contributory factor that may be considered could be innovative or new technologies.

Final Rule Action: After careful consideration of the comments received, we are finalizing the updates to the Master List criteria as proposed. We believe the updates will allow us to appropriately identify and target items posing vulnerabilities to the Trust Funds, to nimbly take action to promote appropriate claim submissions, and to limit improper payments.

b. Notice and Maintenance of the Master List

In § 414.234(b)(2), we proposed that the Master List would be self-updating, at a minimum, annually. We highlighted in our proposal that the "self-updating" process would remain unchanged from the prior regulation and would include applying the criteria to items that appear on the DMEPOS FFS payment schedule. That is, items on the DMEPOS Fee Schedule that meet the payment threshold (for monthly rentals, purchases, or cumulative impacts) will be added to the list when the item is also listed in a future CERT, OIG, or GAO reports, and items not meeting the cost thresholds will be added based on findings of aberrant billing patterns

(meeting the inclusion criteria in section VI.B.3.a of this final rule) that are not otherwise explained. We noted that we believe the inclusion criteria are capable of capturing more current vulnerabilities. We also noted that the current standard process in which items on the list, expire after 10 years if they have not otherwise been removed. We believe this is an appropriate representation of the time needed to achieve behavioral change (such as compliance with Medicare coverage instructions and the correction of behaviors previously resulting in improper payments) and protect the Medicare Trust Funds. We also clarified that if we identify any item currently on the Master List as being included in a subsequent OIG or GAO report, as having a high rate of fraud or unnecessary utilization, or as having a high improper payment rate in the CERT Medicare FFS Supplemental Improper Payment Data report, the item would be maintained on the Master List for 10 years from the date of the most recent report's publication.

We proposed that all other list maintenance processes specified in § 414.234(b) would be maintained with two exceptions: (1) we proposed to allow the Master List to be updated as needed and more frequently than annually (for example, to address emerging billing trends), and (2) we proposed to make technical changes to the language in § 414.234(b) to reflect the new cost thresholds and report years. We proposed to maintain the process outlined in the December 2015 final rule (80 FR 81674) and publish any additions or deletions to the Master List, for any of the reasons and conditions discussed, in a **Federal Register** notice and on the CMS website.

We did not receive any comments in regards to the maintenance of the Master List section of the final rule, and we are finalizing this section as proposed.

Final Rule Action: We are finalizing our proposal at § 414.234(b)(2) that the Master List would be self-updating, at a minimum, annually. We are also finalizing our proposals related to the application of the 10-year timeframe. We are adopting the technical updates to § 414.234(b),

and finalizing our capacity to update the list more frequently than annually, as needed. We will publish any additions or deletions to the Master List, for any of the reasons and conditions discussed, in a **Federal Register** notice and on the CMS website.

4. Required Face-to-Face Encounter and Written Order Prior to Delivery List

a. Creating the Required Face-to-Face Encounter and Written Order Prior to Delivery List

Section 1834(a)(1)(E)(iv) of the Act prohibits payment for motorized or power wheelchairs unless a practitioner conducts a face-to-face examination and writes an order for the item. Section 1834(a)(11)(B) of the Act requires that a practitioner have a face-to-face encounter and written order communicated to the supplier prior to delivery for other specified covered items of DMEPOS, as identified by the Secretary. In the CY 2020 DMEPOS proposed rule (84 FR 38384), we noted the analysis of a 1-year snapshot of claims indicated that approximately 97 percent of beneficiaries receiving DMEPOS had a recent face-to-face encounter (either before or after the DMEPOS date of service). This data was drawn without regard for the item's presence on the DME List of Specified Covered Items (stemming from the November 2012 final rule), which required a face-to-face encounter and a written order prior to delivery. While we believe this information helped to provide important context, we noted that this final rule requires that face-to-face encounters occur prior to the delivery of DMEPOS for those items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List. We proposed to revise § 410.38(d)(1) and § 410.38(d)(2) to limit the face-to-face encounter and written order prior to delivery conditions of payment to only those items selected from the Master List and included on the "Required Face-to-Face Encounter and Written Order Prior to Delivery List." We noted in the CY 2020 DMEPOS proposed rule (84 FR 38384) that this provides us with a broader list of potential items that could be selected, but expect only a subset

of items from the Master List to be subject to the face-to-face encounter and written order prior to delivery requirements, based on those items identified to be of highest risk. We believe tailoring the lists this way significantly reduces any potential supplier/provider impact and may decrease the number of items affected.

We also noted in the CY 2020 DMEPOS proposed rule (84 FR 38384) that since the face-to-face encounter and written order are statutorily required for PMDs, they would be included on the Master List and the Required Face-to-Face Encounter and Written Order Prior Delivery List in accordance with our statutory obligation, and would remain there. In addition, the Master List would include statutorily-identified items, as well as any other items posing potential vulnerability to the Trust Fund, as identified via the proposed Master List inclusion criteria.

We proposed at § 410.38(c), in the definition of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the factors that we may consider when determining which items may be appropriate to require a face-to-face encounter and written order prior to delivery. Specifically, we proposed to consider: operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis. We developed factors that we believe to be indicative of the need for the face-to-face encounter and written order prior to delivery requirements, but noted this list is not exhaustive. We also noted that we did not propose an all-inclusive list of factors to account for the fluidity of program operations and associated vulnerabilities, and we believe this is critical to protect beneficiaries, the program, and industry.

We solicited comments on both our underlying presumption that the list should not be exhaustive, as well as the factors we should consider when selecting an item from the Master

List and including it on the Required Face-to-Face Encounter and Written Order Prior to Delivery List.

We proposed at § 410.38(c)(5) to define the term "face-to-face encounter" as an in-person or telehealth encounter between the treating practitioner and the beneficiary. We further proposed at § 410.38(d)(2) that any telehealth encounter must meet the existing telehealth requirements of § 410.78 and § 414.65. We noted in the CY 2020 DMEPOS proposed rule (84 FR 38384) that under the November 2012 final rule, telehealth services were permitted to be used to satisfy the DME face-to-face encounter requirements. We emphasized in the CY 2020 DMEPOS proposed rule at § 410.38(d)(2) that telehealth services used to meet DMEPOS face-to-face encounter requirements must meet the requirements found at § 410.78 and § 414.65 to support payment of the DMEPOS claim.

Additionally, we specified that the face-to-face encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered and must occur within the 6 months preceding the date of the order/prescription. We proposed to codify at § 410.38(d)(3) that the documentation necessary to support the face-to-face encounter and associated claims for payment includes the written order/prescription and documentation to support medical necessity, which may include the beneficiary's medical history, physical examination, diagnostic tests, findings, progress notes, and plans for treatment. We believe this is reflective of clinical practice and the information necessary to demonstrate medical necessity and the appropriateness of claim payment.

Section 1834(h)(5) of the Act states that for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by orthotists and

prosthetists shall be considered part of the individual's medical record to support documentation created by eligible professionals as described in section 1848(k)(3)(B) of the Act. Documentation from a face-to-face encounter conducted by a treating practitioner, as well as documentation created by an orthotist or prosthetist becomes part of the medical records and if the orthotist or prosthetist notes support the documentation created by eligible professionals described in section 1848(k)(3)(B), they can be used together to support medical necessity of an ordered DMEPOS item. In the event the orthotist or prosthetist documentation does not support the documentation created by the eligible professional, CMS may deny payment.

Our regulations currently require that the written order be communicated prior to delivery for certain specified covered items, within 6 months of the face-to-face encounter, and for PMDs, within 45 days of the face-to-face examination. We proposed to revise § 410.38 to apply the 6-month timeframe to all items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List (including PMDs, which previously required a 45-day timeframe) for uniformity purposes. We believe the 6-month timeframe is relevant, and changing it would create unnecessary confusion since the industry has become accustomed to it.

We noted that the 6-month timing requirement does not supplant other policies that may require more frequent face-to-face encounters for specific items. For example, the National Coverage Determination 240.2 titled "Home Use of Oxygen" requires a face-to-face examination within a month of starting home oxygen therapy.

We also noted in the CY 2020 DMEPOS proposed rule (84 FR 38385) that we do not believe the requirements for the face-to-face encounter and written order prior to delivery would create any new burdens for the medical review process. The Paperwork Reduction Act Record of Information Collection for medical review (CMS-10417; OMB-0938-0969) covers the burden

for responding to documentation requests, generally. Medical review requests require the provider or supplier to submit all documentation necessary to demonstrate compliance with coverage and payment requirements, including the face-to-face encounter.

The comments with regard to the Required Face-to-Face Encounter and Written Order Prior to Delivery List and associated burden, and our responses are set forth below.

Comment: One commenter suggested that CMS add information to the Required Face-to-Face Encounter and Written Order Prior to Delivery List, when items are selected from the Master List, to indicate why items are being subject to a condition of payment.

Response: If an item were chosen to be included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, we plan to include narrative information in the **Federal Register** notice explaining why such item is being subject to a condition of payment. We believe this narrative to be most helpful to stakeholder understanding.

Comment: Commenters urged CMS to ensure that the burden of providing face-to-face encounter documentation, used to comply with our statutory requirements and demonstrate medical need, falls upon the beneficiary's treating practitioner and not community pharmacists who may dispense items of durable medical equipment and supplies.

Response: We agree that the beneficiary's practitioner is charged with creating the documentation of the face-to-face encounter. However, we did not propose to amend the longstanding process whereby additional documentation requests are generally sent to the entity requesting Medicare payment.

Comment: Some commenters urged CMS to permit remote patient monitoring using digitally enabled equipment to satisfy the requirement for face-to-face encounters. Another

commenter stated that CMS should begin to recognize telemedicine as part of the face-to-face procedure.

Response: We recognize the increasing use of technology to achieve clinical oversight of Medicare beneficiaries. While we believe digitally enhanced items serve a clinical purpose, we note that the face-to-face requirement is required by statute and removing the face-to-face requirement for digitally enhanced items is not within our regulatory purview. The statute allows for the face-to-face encounter to be conducted through use of telehealth in accordance with section 1834(m) of the Act, which sets the requirements for Medicare telehealth services. We explicitly codified that Medicare telehealth services used for meeting the face-to- face encounter requirement when ordering DMEPOS items must meet the existing telehealth requirements of § 410.78 and § 414.65. In this way, documentation submitted to support payment for DMEPOS items that was created based upon a telehealth visit must also meet the requirements for telehealth services to support DMEPOS payment.

Comment: Commenters supported the adoption of the uniform 6-month timeframe in which the face-to-face must occur for written orders prior to delivery.

Response: We appreciate the feedback in support of our proposal of the 6-month uniform timeframes.

Final Rule Action: We are finalizing the process for selecting items from the Master List and factors considered in creating the Required Face-to-Face Encounter and Written Order Prior to Delivery List, as proposed. Items that require a face-to-face encounter and written order prior to delivery, will be included on the Master List and the Required Face-to-Face Encounter and Written Order Prior Delivery List in accordance with our statutory obligation. We are finalizing our proposal that documentation submitted to support payment for DMEPOS items that was

created based upon a telehealth visit must also meet the requirements for telehealth services to support DMEPOS payment. We are also finalizing our documentation requirements as proposed, and the requirement for a face-to-face to occur within 6 months, as proposed.

b. Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List

We proposed at § 410.38(c)(8) that CMS would publish a 60-day **Federal Register** notice and post on the CMS' website any item on the Master List that is selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, which is consistent with our current prior authorization practices for items selected from the Master List of Items Frequently Subject to Unnecessary Utilization and included on the Required Prior Authorization List. Similarly, any DMEPOS item selected from the proposed Master List and included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List would be subject to the face-to-face encounter and written order prior to delivery requirement as a national condition of payment, and claims for those items would be denied if the condition of payment is not met.

We proposed at § 410.38(e) to allow the face-to-face encounter and written order prior to delivery requirements to be nationally suspended by CMS for any items at any time, without undertaking a separate rulemaking, except for those items whose inclusion on the Master List (and subsequently, the Required Face-to-Face Encounter and Written Order Prior to Delivery List) was required by statute. For example, we may need to suspend or cease the face-to-face encounter and written order prior to delivery requirements for a particular item(s) for which we determine the face-to-face encounter and written order prior to delivery requirements are unnecessary to meet our previously described objective of limiting waste, fraud, and abuse. We

stated that should we suspend or cease the face-to-face encounter and the written order prior to delivery requirement for any item(s), we would provide stakeholder notification of the suspension on the CMS website.

The comments with regard to the Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List, and our responses are set forth below.

Comment: Some commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. Various commenters suggested we increase the notification period to more than 60 days.

Response: As previously stated earlier in this final rule, we agree that in some cases, a longer notification timeframe may be appropriate. As a result, we are revising the 60-day public notice timeframe for the for Required Face-to-Face Encounter and Written Order Prior to Delivery List to be effective no less than 60 days after a **Federal Register** notice and CMS website posting.

Comment: Some commenters expressed concern that the face-to-face encounter and written order prior to delivery requirements could inadvertently impede beneficiary access to medically necessary care, and suggested such requirements were inappropriate for certain items such as orthotics and prosthetics.

Response: We believe practitioner involvement assists in reducing waste, fraud and abuse, and also helps to ensure that beneficiaries receive DMEPOS to meet their specific needs. We encourage open communication between the beneficiaries and the practitioners, as well as between practitioners and suppliers to ensure that beneficiaries receive medically necessary items in a timely fashion. Practitioners typically have face-to-face encounters in order to assess the beneficiary's clinical need before ordering DMEPOS items. Therefore, we believe the

documentation resulting from this face to face encounter does not create any barrier to treating acute injuries or other clinical needs.

If beneficiaries, practitioners, or suppliers are observing or experiencing significant delays in beneficiary access to DMEPOS due to the imposition of the face-to-face encounter requirement, they are advised to call 1-800-MEDICARE to report their specific concerns.

This rule allows the face-to-face encounter and written order prior to delivery requirements to be nationally suspended by CMS for any items at any time, without undertaking a separate rulemaking, except for those items whose inclusion on the Master List (and subsequently, the Required Face-to-Face Encounter and Written Order Prior to Delivery List) was required by statute. We note that the inclusion of items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List will be monitored for unintended consequences (including beneficiary access concerns).

Final Rule Action: We are revising the 60-day public notice timeframe listed in the Required Face-to-Face Encounter and Written Order Prior to Delivery List to say "The list of items is published in the **Federal Register** and posted on the CMS website. The list is effective no less than 60 days following its publication." We are also finalizing our authority to suspend or cease the face-to-face encounter and written order prior to delivery requirements, with notifications provided on the CMS website, as initially proposed.

5. Required Prior Authorization List

a. Creation and Application of the Required Prior Authorization List

In order to balance minimizing provider and supplier burden with our need to protect the Medicare Trust Funds, we proposed to continue to limit prior authorization to a subset of items on the Master List as currently specified at § 414.234(a)(4). The subset of items requiring prior

authorization are referred to as the Required Prior Authorization List.

OIG and GAO reports, as well as the CERT Medicare FFS Supplemental Improper Payment Data reports, provide national summary data and also often include regional data. Utilization trends within Medicare Contractor localities may show aberrant billing patterns or other identifiable vulnerabilities. At times, claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated among certain suppliers or in certain locations or regions. We proposed to select and implement prior authorization of an item(s) nationally or, in collaboration with the medical review contractors locally. We proposed to revise § 414.234(c)(1)(ii) to state that all suppliers (either nationally or within a contractor jurisdiction) would initially be subject to prior authorization for items identified through a **Federal Register** notice and posted to CMS' website. We also proposed that CMS may elect to exempt suppliers demonstrating compliance from prior authorization for such requirements. We noted in our CY 2020 DMEPOS proposed rule (84 FR 38385) that we believe this meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and provider/supplier burden.

In § 414.234, we proposed that we may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis in selecting items for national or local implementation. For example, items that are the focus of law enforcement investigations may require additional oversight and be appropriate for prior authorization. Likewise, when assessing cost we may prior authorize low dollar items for which the prior authorization decision is applied to consumables that are the same item, rendered to the same beneficiary (for example, items dispensed in units or billed monthly for which the initial decision would remain appropriate), but

would not prior authorize a single low cost item for which the cost of the review would outweigh the anticipated amount of improper payments identified.

We solicited comments on the proposed factors to be considered when selecting an item from the Master List and including it on the Required Prior Authorization List, such as whether the factors could be over-inclusive or under-inclusive.

We noted in the CY 2020 DMEPOS proposed rule (84 FR 38385) that despite the proposed changes in the Master List inclusion criteria, the prior authorization program would continue to apply in all competitive bidding areas because CMS conditions of payment apply under the Medicare DMEPOS Competitive Bidding Program.

We also noted that we recognize that there may be accessories for which stakeholders would like to request prior authorization that may not always appear on the Master List and would not be eligible to include on the Required Prior Authorization List. In addition, we discussed our intent to update the program so that any accessory included on a prior authorization request submitted for an item on the Required Prior Authorization List may nonetheless receive a prior authorization decision for operational simplicity, even if the accessory is not on the Required Prior Authorization List. We stated that the inclusion of such items is voluntary and does not create a condition of payment for items not present on the Required Prior Authorization List. An example of when this occurs is accessories for certain PMDs subject to prior authorization. We stated that the effective date of the final rule may precede shared systems changes that are required to support the addition of accessories that are not on the Master List and the Required Prior Authorization List. Accordingly, there may be a delay in the adoption of this proposed operational change from the date of publication.

We also discussed that historically, we received positive feedback related to the

DMEPOS prior authorization process and the majority of comments have been from suppliers. We encouraged all stakeholders, including those representing beneficiaries and Medicare consumer advocacy organizations, to submit their comments about prior authorization during the public comment period.

We proposed that the items currently subject to prior authorization would be grandfathered into the prior authorization program until the implementation of the first Required Prior Authorization List published subsequent to this rule. This proposal would avoid the administrative and stakeholder burdens associated with the termination of the current prior authorization program and the implementation of a revised program created under this rule.

We proposed to retain the documentation requirements for submitting prior authorization requests at § 414.234(d); however, we proposed to cross reference the payment requirements proposed at § 410.38. In addition, we proposed to retain the process for submitting prior authorization requests and receiving responses, but proposed to restructure § 414.234(e) to conform to the formatting of the preceding paragraphs.

We proposed to maintain the authority to suspend or cease the prior authorization requirement generally or for a particular item or items at any time without undertaking a separate rulemaking. For example, we may need to suspend or cease the prior authorization program due to new payment policies, which may render the prior authorization requirement obsolete or remove the item from Medicare coverage. If we suspend or cease the prior authorization requirement, we would publish a notice in the **Federal Register** and post notification of the suspension on the CMS website and include the date of suspension.

The comments with regard to The Required Prior Authorization List, and our responses are set forth below.

Comment: One commenter suggested that CMS add information to the Required Prior Authorization List, when items are selected from the Master List, to indicate why items are being subject to a condition of payment.

Response: As indicated earlier in this final rule, if an item were selected for inclusion in a required list (meaning the Required Prior Authorization List or Required Face-to-Face Encounter and Written Order Prior to Delivery List), we plan to include information in the **Federal Register** notice explaining why an item is being subject to the condition of payment. We believe this information to be most helpful to stakeholder understanding.

Comment: Commenters urged CMS to be cognizant of items that may be needed imminently when selecting items requiring prior authorization.

Response: We consider multiple factors when determining if an item is appropriate for inclusion on the Required Prior Authorization List, including beneficiary access in a timely fashion. We understand the concerns raised by the comments and will take them into consideration. If beneficiaries, practitioners, or suppliers are observing or experiencing significant delays in beneficiary access to DMEPOS due to their inclusion on the Required Prior Authorization List, they are advised to call 1-800-MEDICARE to report their specific concerns.

Comment: One commenter suggested that prior authorization be reserved for aberrant billers, and proposed relief for billers who participate in standardized data collection. Another commenter suggested that CMS consider compliance incentives to waive prior authorizations and face-to-face requirements for providers that meet such standards.

Response: The prior authorization program is item-based and targets over utilized items billed by all applicable suppliers. In the future, we may elect to exempt suppliers demonstrating compliance from prior authorization requirements for subject items. If so, we will define how

we will identify compliant suppliers in future rulemaking.

Comment: Some commenters expressed support for continuing the prior authorization process, and appreciated the assurance of likely payment in advance of delivering the item and services that is medically necessary for the beneficiary. Another commenter suggested that prior authorization helps limit appeals and corresponding resources.

Response: We appreciate the commenters' feedback on the prior authorization process.

Comment: One commenter expressed support of CMS' proposal to include in the prior authorization decision for PMDs the accessories that are used with the PMD base. Another commenter expressed concern that prior authorizing accessories for which the base was already prior authorized, may create undue delay in the delivery of care. The commenter was also concerned that the addition of accessories was occurring without formal rulemaking.

Response: We appreciate the commenter's support of our proposal to allow accessories to be included on a prior authorization request, at the supplier's discretion. We emphasize that this is voluntary, and prior authorization of accessories is not a condition of payment. We note that although this voluntary action is being implemented, there will be a delay in implementation until systems changes are made to support the addition of accessories. Regarding supplies, as noted earlier, a prior authorization of supplies will be valid over a period of time and will not require a prior authorization for each subsequent claim submission. These procedural operations will be clarified in subregulatory guidance.

Comment: Commenters expressed concern that supplies be prior authorized at the outset of care, with affirmation decisions being extended across multiple Medicare payments, in order to prevent undue burden and potential interruptions in care.

Response: Claims for subsequent and serial rental items will be covered under the initial prior authorization decision for time periods stated in NCDs, LCDs, statutes, regulations, and CMS issued manuals and publication. For example, if a policy for the subject DMEPOS item requires medical necessity documentation to be updated annually, the initial prior authorization decision will cover the claims for the subject DMEPOS item for 12 months.

Comment: Commenters suggested that if a DMEPOS item is subject to prior authorization and receives an affirmative decision, then by default, the prior authorization would extend to all related options, supplies, and accessories. Likewise, commenters believed the decision on the initial item would support claim payment for future repairs, or should the beneficiary require a same or similar item.

Response: While we are trying to be increasingly cohesive in our prior authorization process, and are implementing changes to voluntarily include accessories, we note that reviewers are limited in their review to the documentation submitted with the request. In addition, we will only make payment for medically necessary items, options, supplies and accessories. Thus, submitted documentation must support the medical necessity of any related options, supplies or accessories. Similarly, if a request for payment is being made for a new replacement item, medical necessity must be established for the replacement.

Comment: Some commenters suggested that prior authorization should not be viewed as a fraud and abuse tool but as an efficiency tool. Commenters suggested that Targeted Probe and Educate (TPE) or other pre-payment audits serve as the primary means of curbing abuse.

Response: While we agree prior authorization creates efficiencies, we note that the statutory construct emphasizes the importance of prior authorization in preventing overutilization before the improper payment occurs. Prior authorization provides assurances to both

providers/suppliers and the agency that items or services furnished will likely be covered by Medicare. An affirmation prior authorization decision is provisional because other information that is only available after the claim is submitted may result in a denial. For example, there may be technical issues, such as a duplicate claim, which can only be known only after the claim is submitted.

Final Rule Action: We are finalizing the creation and application process of the Required Prior Authorization List, as proposed.

b. Notice of the Required Prior Authorization List

Section § 414.234 currently requires us to inform the public of items included on the Required Prior Authorization List in the **Federal Register** notice no less than 60 days before implementation. We did not propose any changes to this section. We note that all other prior authorization processes described in § 414.234 not mentioned in this rule remain unchanged.

We believe that it is important that CMS have the authority to require prior authorization for an eligible item(s) (that is, on the Master List) locally to encourage immediate response to shifts in billing patterns, which may be related to potential fraud or abuse, or nationally, as the situation may so dictate. We proposed to maintain our current process, as outlined in § 414.234, and publish a **Federal Register** notice no less than 60 days prior to implementation and post on the CMS website when items are placed on the Required Prior Authorization List.

The comments with regard to the Notice of the Required Prior Authorization List, and our responses are set forth below.

Comment: Some commenters indicated that the 60-day notice was not sufficient time for suppliers to adjust business practices. Various commenters suggested we increase the notification period to more than 60 days.

Response: We did not propose any regulatory changes to the notification process for prior authorization, and plan to maintain the regulatory text indicating that the Required Prior Authorization List is effective no less than 60 days after publication and posting. We note that we have granted longer notification periods, to date, in consideration of both the newness of the programs and the types of items selected.

Final Rule Action: We are maintaining our current Notice of the Required Prior Authorization List process, as outlined in § 414.234. When items are placed on the Required Prior Authorization List, we will publish a **Federal Register** notice no less than 60 days before implementation, and post notification on the CMS website.

6. Standardizing the Written Order/Prescription

We note that through subregulatory guidance and the implementation of several regulations, we have adopted different requirements for orders for different items of DMEPOS. To simplify order/prescription requirements and to reduce confusion, we proposed at § 410.38(d)(1) to adopt one set of required written order/prescription elements for all DMEPOS items.

We believe that the process to obtain DMEPOS items is sufficiently similar across the healthcare environment, and that a standardized order requirement is appropriate and would help promote compliance and reduce the confusion associated with complying with multiple, different order/prescription requirements for DMEPOS items. However, we note that the required timing for the order to be provided (from the treating practitioner to the supplier) would continue to vary for DMEPOS items. We proposed at § 410.38(d) that for those items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery of the item (per statutory requirement); for all

other DMEPOS items, a written order/prescription must be communicated to the supplier prior to claim submission.

We believe the proposed requirements of the standardized DMEPOS orders/prescriptions are commonly included in orders/prescriptions rendered in clinical practice. We believe consistent requirements for all items would prove useful as electronic vendors develop programs in support of electronic records for provider and supplier use. We proposed at § 410.38(d)(1)(i) that the standardized order/prescription require the elements listed here:

- Beneficiary Name or Medicare Beneficiary Identifier (MBI).
- General Description of the item.
- Quantity to be dispensed, if applicable.
- Date.
- Practitioner Name or National Provider Identifier.
- Practitioner Signature.

Traditionally, these required standardized order elements are written on a prescription/order; however, we recognize that these required elements may be found in the beneficiary's medical record. We proposed at § 410.38(d)(1) that CMS' medical review contractors shall consider the totality of the medical records when reviewing for compliance with standardized order/prescription elements.

While the above standardized elements are conditions of payment, we recognize that additional information might be helpful on the order/prescription for clinical practice and quality of care. Information may be added to the order/prescription or found in the beneficiary's medical records but are not conditions of payment. For example, route of administration—such as whether oxygen is delivered via nasal cannula or face mask is not required as a condition of

payment, but may be indicated for good clinical practice.

Current § 410.38(d), (e) and (f) contain written order and documentation requirements specific to equipment that is used for treatment of decubitus ulcers, seat-lifts, and transcutaneous electrical nerve stimulator units. We believe the requirements found at § 410.38(d), (e) and (f) are appropriate for inclusion in the standardized written order/prescription and medical record documentation requirements outlined in the CY 2020 DMEPOS proposed rule. In addition, we believe item-specific coverage requirements may be included in national or local coverage documents, as appropriate. Therefore, we proposed to delete the coverage requirements outlined in § 410.38(d), (e) and (f), and to replace sections § 410.38(d) and (e), with our proposed conditions of payment and process for suspending the face-to-face encounter and written order prior to delivery requirements, respectively.

The comments with regard to standardizing the written order/prescription, and our responses are set forth below.

Comment: We received feedback that the term "date" is not sufficiently specific for reviewers and billing entities to know how to date their order/prescription to comply with regulatory and statutory requirements, as applicable. Some commenters supported the uniform order requirements without issue. In particular, one commenter supported the ability to include either the beneficiary name or the Medicare beneficiary identifier (MBI), and either the prescriber name or his/her national provider identifier (NPI), and suggested this policy be adopted for all other Medicare services. One commenter supported the use of the totality of the medical records to document the order/prescription required elements. A commenter reminded CMS that the significant regulatory updates codified in this rule should be reflected and updated in supporting materials.

Response: We appreciate the commenters' support of our proposal to standardize order requirements and the use of the totality of the medical records to document the order/prescription required elements. The comment suggesting that MBI and NPI would be helpful if adopted across all sectors is outside the scope of this rule. Regarding the comment about the date element, we agree with the commenter that the date element may have been subject to interpretation. Accordingly, we will change "date" to "order date. We will revise its subregulatory guidance to reflect these changes. As noted at § 410.38(d)(1)(ii), a completed order for items on the Required Face-To-Face Encounter And Written Order Prior To Delivery List must occur prior to the item being dispensed. Items not on the list require the order prior to claim submission.

Comment: One commenter requested confirmation whether a standardized order element that is not on the order but is found within the medical record would be considered for payment purposes.

Response: While we believe the basic order requirements imposed by this rule are typical to good clinical practice, we provide reviewers with the capacity to consider the totality of the medical record when a missing or flawed element is clearly documented elsewhere in the record.

Comment: Commenters expressed concern that documentation include quantity to support payment even when the quantity of the item dispensed is one.

Response: We believe the comment is specifically about the written order/prescription included in the documentation required for a face-to-face encounter. As we stated in the CY 2020 DMEPOS proposed rule (84 FR 38379), Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical

condition to support the need for the type and quantity of items ordered. However, we note "quantity, as applicable", is one of the required elements of the order. For many DMEPOS items, the prescription/order will not need to state that "one" is the quantity because quantity is not applicable for those items. An example would be a wheelchair. Alternately, a prescription order for disposable supplies will need to include the quantity to be furnished. When reviewing supporting documentation, the reviewer would expect to see clinical need to support any quantity furnished, whether one DMEPOS item or more.

Comment: One commenter suggested that we update the required elements of the standardized order/prescription to specify that "Practitioner Name or National Provider Identifier (NPI)" refers to the *treating* practitioner.

Response: We agree with commenter's suggestion. Treating practitioner is consistent with our intent, as defined throughout this final rule. We have updated the written order/prescription section to clarify our intent that the practitioner signing the document and including his or her name be the treating practitioner, as defined throughout § 410.38 (c) and (d). It will now explicitly state "Treating Practitioner Name or National Provider Identifier (NPI) and "Treating Practitioner Signature."

Final Rule Action: We are finalizing the order section as proposed in § 410.38(d), with modifications made at § 410.38(d)(1)(i)(D) and § 410.38(d)(1)(i)(E). We are revising the element "Practitioner Name or National Provider Identifier" to say "Treating Practitioner Name or National Provider Identifier (NPI)." and the element "Practitioner Signature" to say "Treating Practitioner Signature." We are also revising the element "date" to say "order date."

C. Miscellaneous Comments

We received several comments that were outside the scope of the CY 2020 DMEPOS proposed rule. While some of these comments were related to prior authorization topics, they were not the issues we addressed in detail in the proposed rule. In the following discussion, we summarize and respond to the comments.

Comment: Some commenters suggested shortening the procedural timeframes provided to the contractors via operational instructions regarding prior authorization decisions.

Response: The prior authorization operational process is outside the scope of this final rule, however, we continually strive to make program improvements. After adding an item to the Required Prior Authorization List, we customize final review and decision timelines for each item. In the December 30, 2015 final rule, we stated that this approach to final timelines provides flexibility to develop a process that involves fewer days, as may be appropriate, and allows us to safeguard beneficiary access to care. This is evident in the process developed for the prior authorization of pressure reducing support surfaces, which allows up to 5 days for both initial and resubmitted requests, while prior authorization of PMDs allows up to 10 days for an initial request and 20 days for a subsequent request.

Comment: One commenter urged CMS to allow for more electronic prior authorization communication to further expedite the process for certain items.

Response: The prior authorization operational process is outside the scope of this final rule, however, we continue to discuss with industry about future enhancements to electronic prior authorization processes. Additionally, our medical review contractors have recently started offering prior authorization request submissions and decisions via their online web portals, in efforts to provide suppliers flexibility in communication approaches.

Comment: Some commenters requested CMS clarify that the electronic documentation generated by e-prescribing platforms is an appropriate source of information that can be relied upon during medical reviews.

Response: The format and use of electronic platforms is outside the scope of this rule.

Comment: Commenters suggested that if a beneficiary receives an affirmative prior authorization decision, it should continue to apply even if the beneficiary changes suppliers or moves locations.

Response: We appreciate these comment. Although this suggestion is outside the scope of this regulation, we note that our current processes outlined in our prior authorization operational guides allow for the prior authorization decision and corresponding claim information to remain with the beneficiary. We assume such transfers would be made in accordance with applicable privacy laws.

Comment: Commenters shared their support of the prior authorization process, but expressed concern about the administrative resources needed to effectuate prior authorization requests, which should be reflected in Medicare payments.

Response: We thank the commenters for sharing their concerns. We believe that some assurance of payment and some protection from future audits may ultimately reduce administrative resources. Adjustments to Medicare payments for items subject to prior authorization is outside the scope of this regulation.

Comment: One commenter expressed concern regarding the application of Medicare rules during the audit process, and believes that this ultimately impacts patient care.

Response: We strive to ensure that patients receive the benefits that they are entitled to, while protecting the Medicare Trust Funds against improper payments. The tools that are

provided in this rule help limit improper payments. In addition, we believe that the increased communication offered by prior authorization helps ensure suppliers that items furnished are covered by Medicare and provide an assurance of likely payment. We note that we have robust oversight processes in place to ensure the accuracy of medical review and prior authorization decision making thereby avoiding impacts to patient care.

Comment: Some commenters expressed concern that items subject to prior authorization should not be subject to additional audit.

Response: Paid claims for which there is an associated affirmed prior authorization decision will be afforded some protection from future audits. However, when the subject claim falls within the CERT annual sample or when a supplier's billing patterns signal potential fraud, inappropriate utilization or changes in billing patterns, the claim may be subject to an audit.

Comment: Some commenters suggested the face-to-face encounter requirement be eliminated.

Response: We do not have the authority to eliminate the face-to-face encounter requirement since it is statutorily mandated.

Comment: Some commenters requested that CMS initially implement new items to prior authorization within a limited geographic scope, prior to expansion, to ensure a smooth transition to national implementation.

Response: We appreciate the commenters' support of our roll-out processes to date. We will continue to evaluate new items to ensure sufficient timeframes are provided when planning national implementation.

Comment: Some commenters suggested methods to align Part C prior authorization activities with the FFS program, and suggested operational improvements to such programs.

Response: We note that changes to the Medicare Advantage program were not proposed and subject to formal notice and comment under this rulemaking, and are outside the scope of this rule.

TABLE 13: MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS

HCPCS	Long Description
A4253	Blood Glucose Test Or Reagent Strips For Home Blood Glucose Monitor, Per 50 Strips
A4351	Intermittent Urinary Catheter; Straight Tip, With Or Without Coating (Teflon, Silicone, Silicone Elastomer, Or Hydrophilic, Etc.), Each
A7025	High Frequency Chest Wall Oscillation System Vest, Replacement For Use With Patient Owned Equipment, Each
E0170	Commode Chair With Integrated Seat Lift Mechanism, Electric, Any Type
E0193	Powered Air Flotation Bed (Low Air Loss Therapy)
E0194	Air Fluidized Bed
E0250	Hospital Bed, Fixed Height, With Any Type Side Rails, With Mattress
E0251	Hospital Bed, Fixed Height, With Any Type Side Rails, Without Mattress
E0255	Hospital Bed, Variable Height, Hi-Lo, With Any Type Side Rails, With Mattress
E0256	Hospital Bed, Variable Height, Hi-Lo, With Any Type Side Rails, Without Mattress
E0260	Hospital Bed, Semi-Electric (Head And Foot Adjustment), With Any Type Side Rails, With Mattress
E0261	Hospital Bed, Semi-Electric (Head And Foot Adjustment), With Any Type Side Rails, Without Mattress
E0265	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), With Any Type Side Rails, With Mattress
E0266	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), With Any Type Side Rails, Without Mattress
E0277	Powered Pressure-Reducing Air Mattress
E0290	Hospital Bed, Fixed Height, Without Side Rails, With Mattress
E0292	Hospital Bed, Variable Height, Hi-Lo, Without Side Rails, With Mattress
E0293	Hospital Bed, Variable Height, Hi-Lo, Without Side Rails, Without Mattress
E0294	Hospital Bed, Semi-Electric (Head And Foot Adjustment), Without Side Rails, With Mattress

HCPCS	Long Description
E0295	Hospital Bed, Semi-Electric (Head And Foot Adjustment), Without Side Rails, Without Mattress
E0296	Hospital Bed, Total Electric (Head, Foot And Height Adjustments). Without Side Rails, With Mattress
E0297	Hospital Bed, Total Electric (Head, Foot And Height Adjustments), Without Side Rails, Without Mattress
E0300	Pediatric Crib, Hospital Grade, Fully Enclosed, With Or Without Top Enclosure
E0301	Hospital Bed, Heavy Duty, Extra Wide, With Weight Capacity Greater Than 350 Pounds, But Less Than Or Equal To 600 Pounds, With Any Type Side Rails, Without Mattress
E0302	Hospital Bed, Extra Heavy Duty, Extra Wide, With Weight Capacity Greater Than 600 Pounds, With Any Type Side Rails, Without Mattress
E0303	Hospital Bed, Heavy Duty, Extra Wide, With Weight Capacity Greater Than 350 Pounds, But Less Than Or Equal To 600 Pounds, With Any Type Side Rails, With Mattress
E0304	Hospital Bed, Extra Heavy Duty, Extra Wide, With Weight Capacity Greater Than 600 Pounds, With Any Type Side Rails, With Mattress
E0316	Safety Enclosure Frame/Canopy For Use With Hospital Bed, Any Type
E0371	Nonpowered Advanced Pressure Reducing Overlay For Mattress, Standard Mattress Length And Width
E0372	Powered Air Overlay For Mattress, Standard Mattress Length And Width
E0373	Nonpowered Advanced Pressure Reducing Mattress
E0424	Stationary Compressed Gaseous Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter, Humidifier, Nebulizer, Cannula Or Mask, And Tubing
E0431	Portable Gaseous Oxygen System, Rental; Includes Portable Container, Regulator, Flowmeter, Humidifier, Cannula Or Mask, And Tubing
E0433	Portable Liquid Oxygen System, Rental; Home Liquefier Used To Fill Portable Liquid Oxygen Containers, Includes Portable Containers, Regulator, Flowmeter, Humidifier, Cannula Or Mask And Tubing, With Or Without Supply Reservoir And Contents Gauge
E0434	Portable Liquid Oxygen System, Rental; Includes Portable Container, Supply Reservoir, Humidifier, Flowmeter, Refill Adaptor, Contents Gauge, Cannula Or Mask, And Tubing
E0439	Stationary Liquid Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter, Humidifier, Nebulizer, Cannula Or Mask, & Tubing
E0462	Rocking Bed With Or Without Side Rails
E0465	Home Ventilator, Any Type, Used With Invasive Interface, (For Example, Tracheostomy Tube)

HCPCS	Long Description
E0466	Home Ventilator, Any Type, Used With Non-Invasive Interface, (For Example, Mask, Chest Shell)
E0470	Respiratory Assist Device, Bi-Level Pressure Capability, Without Backup Rate Feature, Used With Noninvasive Interface, (For Example, Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device))
E0471	Respiratory Assist Device, Bi-Level Pressure Capability, With Back-Up Rate Feature, Used With Noninvasive Interface, (For Example, Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device))
E0472	Respiratory Assist Device, Bi-Level Pressure Capability, With Backup Rate Feature, Used With Invasive Interface, (For Example, Tracheostomy Tube (Intermittent Assist Device With Continuous Positive Airway Pressure Device))
E0483	High Frequency Chest Wall Oscillation Air-Pulse Generator System, (Includes Hoses And Vest), Each
E0550	Humidifier, Durable For Extensive Supplemental Humidification During Ippb Treatments Or Oxygen Delivery
E0575	Nebulizer, Ultrasonic, Large Volume
E0600	Respiratory Suction Pump, Home Model, Portable Or Stationary, Electric
E0601	Continuous Positive Airway Pressure (Cpap) Device
E0617	External Defibrillator With Integrated Electrocardiogram Analysis
E0620	Skin Piercing Device For Collection Of Capillary Blood, Laser, Each
E0630	Patient Lift, Hydraulic Or Mechanical, Includes Any Seat, Sling, Strap(s) Or Pad(s)
E0635	Patient Lift, Electric With Seat Or Sling
E0636	Multipositional Patient Support System, With Integrated Lift, Patient Accessible Controls
E0639	Patient Lift, Moveable From Room To Room With Disassembly And Reassembly, Includes All Components/Accessories
E0640	Patient Lift, Fixed System, Includes All Components/Accessories
E0747	Osteogenesis Stimulator, Electrical, Non-Invasive, Other Than Spinal Applications
E0748	Osteogenesis Stimulator, Electrical, Non-Invasive, Spinal Applications
E0760	Ostogenesis Stimulator, Low Intensity Ultrasound, Non-Invasive
E0781	Ambulatory Infusion Pump, Single Or Multiple Channels, Electric Or Battery Operated, With Administrative Equipment, Worn By Patient
E0784	External Ambulatory Infusion Pump, Insulin
E0791	Parenteral Infusion Pump, Stationary, Single Or Multi-Channel
E0912	Trapeze Bar, Heavy Duty, For Patient Weight Capacity Greater Than 250 Pounds, Free Standing, Complete With Grab Bar

HCPCS	Long Description
E0983	Manual Wheelchair Accessory, Power Add-On To Convert Manual Wheelchair To Motorized Wheelchair, Joystick Control
E0986	Manual Wheelchair Accessory, Push-Rim Activated Power Assist System
E0988	Manual Wheelchair Accessory, Lever-Activated, Wheel Drive, Pair
E1002	Wheelchair Accessory, Power Seating System, Tilt Only
E1003	Wheelchair Accessory, Power Seating System, Recline Only, Without Shear Reduction
E1004	Wheelchair Accessory, Power Seating System, Recline Only, With Mechanical Shear Reduction
E1005	Wheelchair Accessory, Power Seating System, Recline Only, With Power Shear Reduction
E1006	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, Without Shear Reduction
E1007	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, With Mechanical Shear Reduction
E1008	Wheelchair Accessory, Power Seating System, Combination Tilt And Recline, With Power Shear Reduction
E1010	Wheelchair Accessory, Addition To Power Seating System, Power Leg Elevation System, Including Leg Rest, Pair
E1012	Wheelchair Accessory, Addition To Power Seating System, Center Mount Power Elevating Leg Rest/Platform, Complete System, Any Type, Each
E1030	Wheelchair Accessory, Ventilator Tray, Gimbaled
E1035	Multi-Positional Patient Transfer System, With Integrated Seat, Operated By Care Giver, Patient Weight Capacity Up To And Including 300 Pounds
E1036	Multi-Positional Patient Transfer System, Extra-Wide, With Integrated Seat, Operated By Caregiver, Patient Weight Capacity Greater Than 300 Pounds
E1037	Transport Chair, Pediatric Size
E1161	Manual Adult Size Wheelchair, Includes Tilt In Space
E1232	Wheelchair, Pediatric Size, Tilt-In-Space, Folding, Adjustable, With Seating System
E1233	Wheelchair, Pediatric Size, Tilt-In-Space, Rigid, Adjustable, Without Seating System
E1234	Wheelchair, Pediatric Size, Tilt-In-Space, Folding, Adjustable, Without Seating System
E1235	Wheelchair, Pediatric Size, Rigid, Adjustable, With Seating System
E1236	Wheelchair, Pediatric Size, Folding, Adjustable, With Seating System
E1237	Wheelchair, Pediatric Size, Rigid, Adjustable, Without Seating System
E1238	Wheelchair, Pediatric Size, Folding, Adjustable, Without Seating System
E1390	Oxygen Concentrator, Single Delivery Port, Capable Of Delivering 85 Percent Or Greater Oxygen Concentration At The Prescribed Flow Rate

HCPCS	Long Description
E1391	Oxygen Concentrator, Dual Delivery Port, Capable Of Delivering 85 Percent Or Greater Oxygen Concentration At The Prescribed Flow Rate, Each
E1392	Portable Oxygen Concentrator, Rental
E1405	Oxygen And Water Vapor Enriching System With Heated Delivery
E1406	Oxygen And Water Vapor Enriching System Without Heated Delivery
E2000	Gastric Suction Pump, Home Model, Portable Or Stationary, Electric
E2100	Blood Glucose Monitor With Integrated Voice Synthesizer
E2204	Manual Wheelchair Accessory, Nonstandard Seat Frame Depth, 22 To 25 Inches
E2227	Manual Wheelchair Accessory, Gear Reduction Drive Wheel, Each
E2228	Manual Wheelchair Accessory, Wheel Braking System And Lock, Complete, Each
E2310	Power Wheelchair Accessory, Electronic Connection Between Wheelchair Controller And One Power Seating System Motor, Including All Related Electronics, Indicator Feature, Mechanical Function Selection Switch, And Fixed Mounting Hardware
E2311	Power Wheelchair Accessory, Electronic Connection Between Wheelchair Controller And Two Or More Power Seating System Motors, Including All Related Electronics, Indicator Feature, Mechanical Function Selection Switch, And Fixed Mounting Hardware
E2312	Power Wheelchair Accessory, Hand Or Chin Control Interface, Mini-Proportional Remote Joystick, Proportional, Including Fixed Mounting Hardware
E2321	Power Wheelchair Accessory, Hand Control Interface, Remote Joystick, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Fixed Mounting Hardware
E2322	Power Wheelchair Accessory, Hand Control Interface, Multiple Mechanical Switches, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Fixed Mounting Hardware
E2325	Power Wheelchair Accessory, Sip And Puff Interface, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, And Manual Swingaway Mounting Hardware
E2327	Power Wheelchair Accessory, Head Control Interface, Mechanical, Proportional, Including All Related Electronics, Mechanical Direction Change Switch, And Fixed Mounting Hardware
E2328	Power Wheelchair Accessory, Head Control Or Extremity Control Interface, Electronic, Proportional, Including All Related Electronics And Fixed Mounting Hardware
E2329	Power Wheelchair Accessory, Head Control Interface, Contact Switch Mechanism, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, Mechanical Direction Change Switch, Head Array, And Fixed Mounting Hardware

HCPCS	Long Description
E2330	Power Wheelchair Accessory, Head Control Interface, Proximity Switch Mechanism, Nonproportional, Including All Related Electronics, Mechanical Stop Switch, Mechanical Direction Change Switch, Head Array, And Fixed Mounting Hardware
E2351	Power Wheelchair Accessory, Electronic Interface To Operate Speech Generating Device Using Power Wheelchair Control Interface
E2368	Power Wheelchair Component, Drive Wheel Motor, Replacement Only
E2369	Power Wheelchair Component, Drive Wheel Gear Box, Replacement Only
E2370	Power Wheelchair Component, Integrated Drive Wheel Motor And Gear Box Combination, Replacement Only
E2373	Power Wheelchair Accessory, Hand Or Chin Control Interface, Compact Remote Joystick, Proportional, Including Fixed Mounting Hardware
E2374	Power Wheelchair Accessory, Hand Or Chin Control Interface, Standard Remote Joystick (Not Including Controller), Proportional, Including All Related Electronics And Fixed Mounting Hardware, Replacement Only
E2375	Power Wheelchair Accessory, Non-Expandable Controller, Including All Related Electronics And Mounting Hardware, Replacement Only
E2376	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics And Mounting Hardware, Replacement Only
E2377	Power Wheelchair Accessory, Expandable Controller, Including All Related Electronics And Mounting Hardware, Upgrade Provided At Initial Issue
E2378	Power Wheelchair Component, Actuator, Replacement Only
E2402	Negative Pressure Wound Therapy Electrical Pump, Stationary Or Portable
E2614	Positioning Wheelchair Back Cushion, Posterior, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware
E2616	Positioning Wheelchair Back Cushion, Posterior-Lateral, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware
E2620	Positioning Wheelchair Back Cushion, Planar Back With Lateral Supports, Width Less Than 22 Inches, Any Height, Including Any Type Mounting Hardware
E2621	Positioning Wheelchair Back Cushion, Planar Back With Lateral Supports, Width 22 Inches Or Greater, Any Height, Including Any Type Mounting Hardware
E2626	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Adjustable
E2627	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Adjustable Rancho Type
E2628	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Reclining
E2629	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support Attached To Wheelchair, Balanced, Friction Arm Support (Friction Dampening To

HCPCS	Long Description
	Proximal And Distal Joints)
E2630	Wheelchair Accessory, Shoulder Elbow, Mobile Arm Support, Monosuspension Arm And Hand Support, Overhead Elbow Forearm Hand Sling Support, Yoke Type Suspension Support
K0002	Standard Hemi (Low Seat) Wheelchair
K0003	Lightweight Wheelchair
K0004	High Strength, Lightweight Wheelchair
K0005	Ultralightweight Wheelchair
K0006	Heavy Duty Wheelchair
K0007	Extra Heavy Duty Wheelchair
K0009	Other Manual Wheelchair/Base
K0455	Infusion Pump Used For Uninterrupted Parenteral Administration Of Medication, (For example, Epoprostenol Or Treprostinol)
K0606	Automatic External Defibrillator, With Integrated Electrocardiogram Analysis, Garment Type
K0609	Replacement Electrodes For Use With Automated External Defibrillator, Garment Type Only, Each
K0730	Controlled Dose Inhalation Drug Delivery System
K0738	Portable Gaseous Oxygen System, Rental; Home Compressor Used To Fill Portable Oxygen Cylinders; Includes Portable Containers, Regulator, Flowmeter, Humidifier, Cannula Or Mask, And Tubing
K0800	Power Operated Vehicle, Group 1 Standard, Patient Weight Capacity Up To And Including 300 Pounds
K0801	Power Operated Vehicle, Group 1 Heavy Duty, Patient Weight Capacity, 301 To 450 Pounds
K0802	Power Operated Vehicle, Group 1 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds
K0806	Power Operated Vehicle, Group 2 Standard, Patient Weight Capacity Up To And Including 300 Pounds
K0807	Power Operated Vehicle, Group 2 Heavy Duty, Patient Weight Capacity 301 To 450 Pounds
K0808	Power Operated Vehicle, Group 2 Very Heavy Duty, Patient Weight Capacity 451 To 600 Pounds
K0813	Power Wheelchair, Group 1 Standard, Portable, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds
K0814	Power Wheelchair, Group 1 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0815	Power Wheelchair, Group 1 Standard, Sling/Solid Seat And Back, Patient Weight Capacity Up To And Including 300 Pounds
K0816	Power Wheelchair, Group 1 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0820	Power Wheelchair, Group 2 Standard, Portable, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds

HCPCS	Long Description
K0821	Power Wheelchair, Group 2 Standard, Portable, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0822	Power Wheelchair, Group 2 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0823	Power Wheelchair, Group 2 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0824	Power Wheelchair, Group 2 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0825	Power Wheelchair, Group 2 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0826	Power Wheelchair, Group 2 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0827	Power Wheelchair, Group 2 Very Heavy Duty, Captains Chair, Patient Weight Capacity 451 To 600 Pounds
K0828	Power Wheelchair, Group 2 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
K0829	Power Wheelchair, Group 2 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More
K0835	Power Wheelchair, Group 2 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0836	Power Wheelchair, Group 2 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0837	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0838	Power Wheelchair, Group 2 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0839	Power Wheelchair, Group 2 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0840	Power Wheelchair, Group 2 Extra Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
K0841	Power Wheelchair, Group 2 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0842	Power Wheelchair, Group 2 Standard, Multiple Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0843	Power Wheelchair, Group 2 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0848	Power Wheelchair, Group 3 Standard, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0849	Power Wheelchair, Group 3 Standard, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0850	Power Wheelchair, Group 3 Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0851	Power Wheelchair, Group 3 Heavy Duty, Captains Chair, Patient Weight Capacity 301 To 450 Pounds

HCPCS	Long Description
K0852	Power Wheelchair, Group 3 Very Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0853	Power Wheelchair, Group 3 Very Heavy Duty, Captains Chair, Patient Weight Capacity, 451 To 600 Pounds
K0854	Power Wheelchair, Group 3 Extra Heavy Duty, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
K0855	Power Wheelchair, Group 3 Extra Heavy Duty, Captains Chair, Patient Weight Capacity 601 Pounds Or More
K0856	Power Wheelchair, Group 3 Standard, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0857	Power Wheelchair, Group 3 Standard, Single Power Option, Captains Chair, Patient Weight Capacity Up To And Including 300 Pounds
K0858	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0859	Power Wheelchair, Group 3 Heavy Duty, Single Power Option, Captains Chair, Patient Weight Capacity 301 To 450 Pounds
K0860	Power Wheelchair, Group 3 Very Heavy Duty, Single Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0861	Power Wheelchair, Group 3 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 300 Pounds
K0862	Power Wheelchair, Group 3 Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 301 To 450 Pounds
K0863	Power Wheelchair, Group 3 Very Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 451 To 600 Pounds
K0864	Power Wheelchair, Group 3 Extra Heavy Duty, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity 601 Pounds Or More
L0631	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L0635	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panel(S), Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment
L0636	Lumbar Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces

HCPCS	Long Description
	Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Custom Fabricated
L0637	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L0638	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated
L0639	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L0640	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Custom Fabricated
L0648	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf
L0650	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-

HCPCS	Long Description
	Shelf
L0651	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xyphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf
L1680	Hip Orthosis, Abduction Control Of Hip Joints, Dynamic, Pelvic Control, Adjustable Hip Motion Control, Thigh Cuffs (Rancho Hip Action Type), Custom Fabricated
L1685	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Custom Fabricated
L1686	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting And Adjustment
L1690	Combination, Bilateral, Lumbo-Sacral, Hip, Femur Orthosis Providing Adduction And Internal Rotation Control, Prefabricated, Includes Fitting And Adjustment
L1700	Legg Perthes Orthosis, (Toronto Type), Custom-Fabricated
L1710	Legg Perthes Orthosis, (Newington Type), Custom Fabricated
L1720	Legg Perthes Orthosis, Trilateral, (Tachdijan Type), Custom-Fabricated
L1730	Legg Perthes Orthosis, (Scottish Rite Type), Custom-Fabricated
L1755	Legg Perthes Orthosis, (Patten Bottom Type), Custom-Fabricated
L1832	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1833	Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The Shelf
L1834	Knee Orthosis, Without Knee Joint, Rigid, Custom-Fabricated
L1840	Knee Orthosis, Derotation, Medial-Lateral, Anterior Cruciate Ligament, Custom Fabricated
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated

HCPCS	Long Description
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated
L1847	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
L1848	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated, Off-The-Shelf
L1851	Knee Orthosis (Ko), Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf
L1852	Knee Orthosis (Ko), Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint (Unicentric Or Polycentric), Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Off-The-Shelf
L1860	Knee Orthosis, Modification Of Supracondylar Prosthetic Socket, Custom-Fabricated (Sk)
L1907	Ankle Orthosis, Supramalleolar With Straps, With Or Without Interface/Pads, Custom Fabricated
L1932	Afo, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated
L1945	Ankle Foot Orthosis, Plastic, Rigid Anterior Tibial Section (Floor Reaction), Custom-Fabricated
L1950	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic, Custom-Fabricated
L1951	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated
L2000	Knee Ankle Foot Orthosis, Single Upright, Free Knee, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar Ak Orthosis), Custom-

HCPCS	Long Description
	Fabricated
L2005	Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Any Type Activation, Includes Ankle Joint, Any Type, Custom Fabricated
L2010	Knee Ankle Foot Orthosis, Single Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar Ak Orthosis), Without Knee Joint, Custom-Fabricated
L2020	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Double Bar Ak Orthosis), Custom-Fabricated
L2030	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs, (Double Bar Ak Orthosis), Without Knee Joint, Custom Fabricated
L2034	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, With Or Without Free Motion Knee, Medial Lateral Rotation Control, With Or Without Free Motion Ankle, Custom Fabricated
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated
L2037	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated
L2038	Knee Ankle Foot Orthosis, Full Plastic, With Or Without Free Motion Knee, Multi-Axis Ankle, Custom Fabricated
L2050	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Hip Joint, Pelvic Band/Belt, Custom-Fabricated
L2060	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Ball Bearing Hip Joint, Pelvic Band/ Belt, Custom-Fabricated
L2106	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated
L2108	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Custom-Fabricated
L2114	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment
L2116	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment
L2126	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated
L2128	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Custom-Fabricated
L2132	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment
L2134	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Semi-Rigid,

HCPCS	Long Description
	Prefabricated, Includes Fitting And Adjustment
L2136	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment
L2350	Addition To Lower Extremity, Prosthetic Type, (Bk) Socket, Molded To Patient Model, (Used For Ptb Afo Orthoses)
L2510	Addition To Lower Extremity, Thigh/Weight Bearing, Quadri- Lateral Brim, Molded To Patient Model
L2525	Addition To Lower Extremity, Thigh/Weight Bearing, Ischial Containment/Narrow M-L Brim Molded To Patient Model
L2526	Addition To Lower Extremity, Thigh/Weight Bearing, Ischial Containment/Narrow M-L Brim, Custom Fitted
L2570	Addition To Lower Extremity, Pelvic Control, Hip Joint, Clevis Type Two Position Joint, Each
L2627	Addition To Lower Extremity, Pelvic Control, Plastic, Molded To Patient Model, Reciprocating Hip Joint And Cables
L2628	Addition To Lower Extremity, Pelvic Control, Metal Frame, Reciprocating Hip Joint And Cables
L3330	Lift, Elevation, Metal Extension (Skate)
L3671	Shoulder Orthosis, Shoulder Joint Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3674	Shoulder Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, With Or Without Nontorsion Joint/Turnbuckle, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3720	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Free Motion, Custom-Fabricated
L3730	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Extension/ Flexion Assist, Custom-Fabricated
L3740	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Adjustable Position Lock With Active Control, Custom-Fabricated
L3761	Elbow Orthosis (Eo), With Adjustable Position Locking Joint(S), Prefabricated, Off-The-Shelf
L3763	Elbow Wrist Hand Orthosis, Rigid, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3764	Elbow Wrist Hand Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3765	Elbow Wrist Hand Finger Orthosis, Rigid, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment

HCPCS	Long Description
L3766	Elbow Wrist Hand Finger Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3900	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Wrist Or Finger Driven, Custom-Fabricated
L3901	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Cable Driven, Custom-Fabricated
L3904	Wrist Hand Finger Orthosis, External Powered, Electric, Custom-Fabricated
L3905	Wrist Hand Orthosis, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3960	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment
L3961	Shoulder Elbow Wrist Hand Orthosis, Shoulder Cap Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3962	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Erbs Palsey Design, Prefabricated, Includes Fitting And Adjustment
L3967	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3971	Shoulder Elbow Wrist Hand Orthosis, Shoulder Cap Design, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3973	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3975	Shoulder Elbow Wrist Hand Finger Orthosis, Shoulder Cap Design, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3976	Shoulder Elbow Wrist Hand Finger Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Without Joints, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3977	Shoulder Elbow Wrist Hand Finger Orthosis, Shoulder Cap Design, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment

HCPCS	Long Description
L3978	Shoulder Elbow Wrist Hand Finger Orthosis, Abduction Positioning (Airplane Design), Thoracic Component And Support Bar, Includes One Or More Nontorsion Joints, Elastic Bands, Turnbuckles, May Include Soft Interface, Straps, Custom Fabricated, Includes Fitting And Adjustment
L3981	Upper Extremity Fracture Orthosis, Humeral, Prefabricated, Includes Shoulder Cap Design, With Or Without Joints, Forearm Section, May Include Soft Interface, Straps, Includes Fitting And Adjustments
L4010	Replace Trilateral Socket Brim
L4020	Replace Quadrilateral Socket Brim, Molded To Patient Model
L4030	Replace Quadrilateral Socket Brim, Custom Fitted
L4130	Replace Pretibial Shell
L4631	Ankle Foot Orthosis, Walking Boot Type, Varus/Valgus Correction, Rocker Bottom, Anterior Tibial Shell, Soft Interface, Custom Arch Support, Plastic Or Other Material, Includes Straps And Closures, Custom Fabricated
L5000	Partial Foot, Shoe Insert With Longitudinal Arch, Toe Filler
L5010	Partial Foot, Molded Socket, Ankle Height, With Toe Filler
L5020	Partial Foot, Molded Socket, Tibial Tubercle Height, With Toe Filler
L5050	Ankle, Symes, Molded Socket, Sach Foot
L5060	Ankle, Symes, Metal Frame, Molded Leather Socket, Articulated Ankle/Foot
L5100	Below Knee, Molded Socket, Shin, Sach Foot
L5105	Below Knee, Plastic Socket, Joints And Thigh Lacer, Sach Foot
L5150	Knee Disarticulation (Or Through Knee), Molded Socket, External Knee Joints, Shin, Sach Foot
L5160	Knee Disarticulation (Or Through Knee), Molded Socket, Bent Knee Configuration, External Knee Joints, Shin, Sach Foot
L5200	Above Knee, Molded Socket, Single Axis Constant Friction Knee, Shin, Sach Foot
L5210	Above Knee, Short Prosthesis, No Knee Joint (Stubbies), With Foot Blocks, No Ankle Joints, Each
L5220	Above Knee, Short Prosthesis, No Knee Joint (Stubbies), With Articulated Ankle/Foot, Dynamically Aligned, Each
L5230	Above Knee, For Proximal Femoral Focal Deficiency, Constant Friction Knee, Shin, Sach Foot
L5250	Hip Disarticulation, Canadian Type; Molded Socket, Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot
L5270	Hip Disarticulation, Tilt Table Type; Molded Socket, Locking Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot
L5280	Hemipelvectomy, Canadian Type; Molded Socket, Hip Joint, Single Axis Constant Friction Knee, Shin, Sach Foot
L5301	Below Knee, Molded Socket, Shin, Sach Foot, Endoskeletal System

HCPCS	Long Description
L5312	Knee Disarticulation (Or Through Knee), Molded Socket, Single Axis Knee, Pylon, Sach Foot, Endoskeletal System
L5321	Above Knee, Molded Socket, Open End, Sach Foot, Endoskeletal System, Single Axis Knee
L5331	Hip Disarticulation, Canadian Type, Molded Socket, Endoskeletal System, Hip Joint, Single Axis Knee, Sach Foot
L5341	Hemipelvectomy, Canadian Type, Molded Socket, Endoskeletal System, Hip Joint, Single Axis Knee, Sach Foot
L5400	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment, Suspension, And One Cast Change, Below Knee
L5420	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Including Fitting, Alignment And Suspension And One Cast Change Ak Or Knee Disarticulation
L5430	Immediate Post Surgical Or Early Fitting, Application Of Initial Rigid Dressing, Incl. Fitting, Alignment And Suspension, Ak Or Knee Disarticulation, Each Additional Cast Change And Realignment
L5460	Immediate Post Surgical Or Early Fitting, Application Of Non-Weight Bearing Rigid Dressing, Above Knee
L5500	Initial, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5505	Initial, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Direct Formed
L5510	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5520	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5530	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5535	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, No Cover, Sach Foot, Prefabricated, Adjustable Open End Socket
L5540	Preparatory, Below Knee Ptb Type Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Model
L5560	Preparatory, Above Knee- Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Plaster Socket, Molded To Model
L5570	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Direct Formed
L5580	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Model
L5585	Preparatory, Above Knee - Knee Disarticulation, Ischial Level Socket,

HCPCS	Long Description
	Non-Alignable System, Pylon, No Cover, Sach Foot, Prefabricated Adjustable Open End Socket
L5590	Preparatory, Above Knee - Knee Disarticulation Ischial Level Socket, Non-Alignable System, Pylon No Cover, Sach Foot, Laminated Socket, Molded To Model
L5595	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Thermoplastic Or Equal, Molded To Patient Model
L5600	Preparatory, Hip Disarticulation-Hemipelvectomy, Pylon, No Cover, Sach Foot, Laminated Socket, Molded To Patient Model
L5610	Addition To Lower Extremity, Endoskeletal System, Above Knee, Hydracadence System
L5611	Addition To Lower Extremity, Endoskeletal System, Above Knee - Knee Disarticulation, 4 Bar Linkage, With Friction Swing Phase Control
L5613	Addition To Lower Extremity, Endoskeletal System, Above Knee-Knee Disarticulation, 4 Bar Linkage, With Hydraulic Swing Phase Control
L5614	Addition To Lower Extremity, Exoskeletal System, Above Knee-Knee Disarticulation, 4 Bar Linkage, With Pneumatic Swing Phase Control
L5616	Addition To Lower Extremity, Endoskeletal System, Above Knee, Universal Multiplex System, Friction Swing Phase Control
L5617	Addition To Lower Extremity, Quick Change Self-Aligning Unit, Above Knee Or Below Knee, Each
L5626	Addition To Lower Extremity, Test Socket, Hip Disarticulation
L5628	Addition To Lower Extremity, Test Socket, Hemipelvectomy
L5638	Addition To Lower Extremity, Below Knee, Leather Socket
L5639	Addition To Lower Extremity, Below Knee, Wood Socket
L5640	Addition To Lower Extremity, Knee Disarticulation, Leather Socket
L5642	Addition To Lower Extremity, Above Knee, Leather Socket
L5643	Addition To Lower Extremity, Hip Disarticulation, Flexible Inner Socket, External Frame
L5644	Addition To Lower Extremity, Above Knee, Wood Socket
L5645	Addition To Lower Extremity, Below Knee, Flexible Inner Socket, External Frame
L5646	Addition To Lower Extremity, Below Knee, Air, Fluid, Gel Or Equal, Cushion Socket
L5647	Addition To Lower Extremity, Below Knee Suction Socket
L5648	Addition To Lower Extremity, Above Knee, Air, Fluid, Gel Or Equal, Cushion Socket
L5649	Addition To Lower Extremity, Ischial Containment/Narrow M-L Socket
L5650	Additions To Lower Extremity, Total Contact, Above Knee Or Knee Disarticulation Socket
L5651	Addition To Lower Extremity, Above Knee, Flexible Inner Socket, External Frame
L5653	Addition To Lower Extremity, Knee Disarticulation, Expandable Wall Socket

HCPCS	Long Description
L5661	Addition To Lower Extremity, Socket Insert, Multi-Durometer Symes
L5665	Addition To Lower Extremity, Socket Insert, Multi-Durometer, Below Knee
L5671	Addition To Lower Extremity, Below Knee / Above Knee Suspension Locking Mechanism (Shuttle, Lanyard Or Equal), Excludes Socket Insert
L5673	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric Or Equal, For Use With Locking Mechanism
L5677	Additions To Lower Extremity, Below Knee, Knee Joints, Polycentric, Pair
L5679	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric Or Equal, Not For Use With Locking Mechanism
L5681	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated Socket Insert For Congenital Or Atypical Traumatic Amputee, Silicone Gel, Elastomeric Or Equal, For Use With Or Without Locking Mechanism, Initial Only (For Other Than Initial, Use Code L5673 Or L5679)
L5682	Addition To Lower Extremity, Below Knee, Thigh Lacer, Gluteal/Ischial, Molded
L5683	Addition To Lower Extremity, Below Knee/Above Knee, Custom Fabricated Socket Insert For Other Than Congenital Or Atypical Traumatic Amputee, Silicone Gel, Elastomeric Or Equal, For Use With Or Without Locking Mechanism, Initial Only (For Other Than Initial, Use Code L5673 Or L5679)
L5700	Replacement, Socket, Below Knee, Molded To Patient Model
L5701	Replacement, Socket, Above Knee/Knee Disarticulation, Including Attachment Plate, Molded To Patient Model
L5702	Replacement, Socket, Hip Disarticulation, Including Hip Joint, Molded To Patient Model
L5703	Ankle, Symes, Molded To Patient Model, Socket Without Solid Ankle Cushion Heel (Sach) Foot, Replacement Only
L5704	Custom Shaped Protective Cover, Below Knee
L5705	Custom Shaped Protective Cover, Above Knee
L5706	Custom Shaped Protective Cover, Knee Disarticulation
L5707	Custom Shaped Protective Cover, Hip Disarticulation
L5711	Additions Exoskeletal Knee-Shin System, Single Axis, Manual Lock, Ultra-Light Material
L5716	Addition, Exoskeletal Knee-Shin System, Polycentric, Mechanical Stance Phase Lock
L5718	Addition, Exoskeletal Knee-Shin System, Polycentric, Friction Swing And Stance Phase Control

HCPCS	Long Description
L5722	Addition, Exoskeletal Knee-Shin System, Single Axis, Pneumatic Swing, Friction Stance Phase Control
L5724	Addition, Exoskeletal Knee-Shin System, Single Axis, Fluid Swing Phase Control
L5726	Addition, Exoskeletal Knee-Shin System, Single Axis, External Joints Fluid Swing Phase Control
L5728	Addition, Exoskeletal Knee-Shin System, Single Axis, Fluid Swing And Stance Phase Control
L5780	Addition, Exoskeletal Knee-Shin System, Single Axis, Pneumatic/Hydra Pneumatic Swing Phase Control
L5781	Addition To Lower Limb Prosthesis, Vacuum Pump, Residual Limb Volume Management And Moisture Evacuation System
L5782	Addition To Lower Limb Prosthesis, Vacuum Pump, Residual Limb Volume Management And Moisture Evacuation System, Heavy Duty
L5785	Addition, Exoskeletal System, Below Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5790	Addition, Exoskeletal System, Above Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5795	Addition, Exoskeletal System, Hip Disarticulation, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5810	Addition, Endoskeletal Knee-Shin System, Single Axis, Manual Lock
L5811	Addition, Endoskeletal Knee-Shin System, Single Axis, Manual Lock, Ultra-Light Material
L5812	Addition, Endoskeletal Knee-Shin System, Single Axis, Friction Swing And Stance Phase Control (Safety Knee)
L5814	Addition, Endoskeletal Knee-Shin System, Polycentric, Hydraulic Swing Phase Control, Mechanical Stance Phase Lock
L5816	Addition, Endoskeletal Knee-Shin System, Polycentric, Mechanical Stance Phase Lock
L5818	Addition, Endoskeletal Knee-Shin System, Polycentric, Friction Swing, And Stance Phase Control
L5822	Addition, Endoskeletal Knee-Shin System, Single Axis, Pneumatic Swing, Friction Stance Phase Control
L5824	Addition, Endoskeletal Knee-Shin System, Single Axis, Fluid Swing Phase Control
L5826	Addition, Endoskeletal Knee-Shin System, Single Axis, Hydraulic Swing Phase Control, With Miniature High Activity Frame
L5828	Addition, Endoskeletal Knee-Shin System, Single Axis, Fluid Swing And Stance Phase Control
L5830	Addition, Endoskeletal Knee-Shin System, Single Axis, Pneumatic/ Swing Phase Control
L5840	Addition, Endoskeletal Knee/Shin System, 4-Bar Linkage Or Multiaxial, Pneumatic Swing Phase Control

HCPCS	Long Description
L5845	Addition, Endoskeletal, Knee-Shin System, Stance Flexion Feature, Adjustable
L5848	Addition To Endoskeletal Knee-Shin System, Fluid Stance Extension, Dampening Feature, With Or Without Adjustability
L5856	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Microprocessor Control Feature, Swing And Stance Phase, Includes Electronic Sensor(S), Any Type
L5857	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Microprocessor Control Feature, Swing Phase Only, Includes Electronic Sensor(S), Any Type
L5858	Addition To Lower Extremity Prosthesis, Endoskeletal Knee Shin System, Microprocessor Control Feature, Stance Phase Only, Includes Electronic Sensor(S), Any Type
L5859	Addition To Lower Extremity Prosthesis, Endoskeletal Knee-Shin System, Powered And Programmable Flexion/Extension Assist Control, Includes Any Type Motor(S)
L5920	Addition, Endoskeletal System, Above Knee Or Hip Disarticulation, Alignable System
L5930	Addition, Endoskeletal System, High Activity Knee Control Frame
L5940	Addition, Endoskeletal System, Below Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5950	Addition, Endoskeletal System, Above Knee, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5960	Addition, Endoskeletal System, Hip Disarticulation, Ultra-Light Material (Titanium, Carbon Fiber Or Equal)
L5961	Addition, Endoskeletal System, Polycentric Hip Joint, Pneumatic Or Hydraulic Control, Rotation Control, With Or Without Flexion And/Or Extension Control
L5962	Addition, Endoskeletal System, Below Knee, Flexible Protective Outer Surface Covering System
L5964	Addition, Endoskeletal System, Above Knee, Flexible Protective Outer Surface Covering System
L5966	Addition, Endoskeletal System, Hip Disarticulation, Flexible Protective Outer Surface Covering System
L5968	Addition To Lower Limb Prosthesis, Multiaxial Ankle With Swing Phase Active Dorsiflexion Feature
L5973	Endoskeletal Ankle Foot System, Microprocessor Controlled Feature, Dorsiflexion And/Or Plantar Flexion Control, Includes Power Source
L5976	All Lower Extremity Prostheses, Energy Storing Foot (Seattle Carbon Copy Ii Or Equal)
L5979	All Lower Extremity Prosthesis, Multi-Axial Ankle, Dynamic Response Foot, One Piece System
L5980	All Lower Extremity Prostheses, Flex Foot System
L5981	All Lower Extremity Prostheses, Flex-Walk System Or Equal

HCPCS	Long Description
L5982	All Exoskeletal Lower Extremity Prostheses, Axial Rotation Unit
L5984	All Endoskeletal Lower Extremity Prosthesis, Axial Rotation Unit, With Or Without Adjustability
L5986	All Lower Extremity Prostheses, Multi-Axial Rotation Unit (Mcp Or Equal)
L5987	All Lower Extremity Prosthesis, Shank Foot System With Vertical Loading Pylon
L5988	Addition To Lower Limb Prosthesis, Vertical Shock Reducing Pylon Feature
L5990	Addition To Lower Extremity Prosthesis, User Adjustable Heel Height
L8035	Custom Breast Prosthesis, Post Mastectomy, Molded To Patient Model
V2531	Contact Lens, Scleral, Gas Permeable, Per Lens (For Contact Lens Modification, See 92325)

VII. DMEPOS Competitive Bidding Program (CBP) 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 revise the existing DMEPOS Competitive Bidding Program (CBP) change of ownership (CHOW) regulations in § 414.422(d) in recognition of the fact that CHOWs may occur on shorter timeframes than our regulations previously contemplated. We also proposed to revise § 414.423(f) for the submission of a hearing request in notices of breach of contract.

B. Proposed Amendments

We proposed to revise the following amendments in § 414.422(d) as follows:

- We proposed to add the acronym “CHOW” after the title of the paragraph and use the acronym throughout the section where we previously wrote out in full text “change of ownership”.
- We proposed to remove the notification requirement at paragraph (d)(1) because we no

longer believe it is necessary for CMS to be notified 60 days in advance when a contract supplier is negotiating a CHOW. In past rounds of the CBP, there have been situations in which contract suppliers have undergone CHOWs within the 60-day timeframe and they were unable to meet the 60-day notice requirement due to circumstances that were not fully within their control. We recognize that the 60-day notice requirement is a bit onerous and as such we proposed to remove paragraph (d)(1) in its entirety. We also proposed to redesignate and reorganize the remaining text of paragraph (d).

- We proposed to remove the distinction of a "new entity" from paragraph (d)(2)(ii) in its entirety, and retain the successor entity requirements in paragraph (d)(2)(i) with changes, as we are aligning the CHOW requirements for all entities, regardless of whether a "new" entity is formed as a result of the CHOW. We also proposed to revise the requirement to submit the documentation described in § 414.414(b) through (d) from 30 days prior to the anticipated effective date of the CHOW to instead require submission prior to the effective date of the CHOW. We further proposed to change the requirement on submission of a signed novation agreement 30 days before the CHOW to instead require that the novation agreement be submitted by the successor entity no later than 10 days after the effective date of the CHOW. We want to allow flexibility for the timing of submission of documents since it may not always be possible for the successor entity to submit the applicable documentation 30 days before the anticipated effective date of the CHOW. Through our education and outreach efforts, we will encourage the successor entity to work with CMS to submit draft documentation as far in advance as possible for CMS to review to ensure that the novation agreement is acceptable to CMS. We believe shortening the timeframe for submission from 30 days to 10 days will expedite CMS's determination on whether to allow transfer of the contract to the successor

entity. We also proposed that the successor entity must submit a novation agreement that states that it assumes all obligations under the contract.

- We proposed to remove the phrase "new qualified" before "entity" and replace it with the term "successor" in paragraph (d)(3) as this is applicable to all successor entities. We also proposed to add the term "may" to make it clear that the transfer of the entire contract to a successor entity is at CMS' discretion upon CMS' review of all required documentation. The revision will align with existing language in paragraph (d)(4), which specifies that CMS may transfer the portion of the contract if certain conditions are met.

- We proposed to revise paragraph (d)(4) by removing the "e.g." parenthetical after "distinct company" to retain only the example of a subsidiary, and noting it as "for example" as we realized that it is the clearest example. In addition, some of the other examples were not accurate (for example, a sole proprietor) and this could lead to confusion. We also proposed to remove the reference to "new qualified" before "entity" and replace it with the term "successor," as the resulting entity in a transfer of a portion of the contract may not result in a "new" entity but will always result in a "successor" entity. In addition, we proposed to remove the phrase "new qualified owner who" in paragraph (d)(4)(i) and replace it with "successor entity that" to align with the language used throughout § 414.422(d). We also proposed to remove the acronym "i.e." and replace it with "that is."

In § 414.423(f)(2), we require that a request for a hearing be "received by" the Competitive Bidding Implementation Contractor (CBIC) within 30 days from the date of the notice of breach of contract. We proposed to revise paragraph (f)(2) to specify that the request for a hearing must be "submitted to" the CBIC rather than "received by" the CBIC within 30 days from the date of the notice of breach of contract. Previously, the CBIC was only able to

receive a written request via mail or fax for a hearing from a contract supplier, however, now contract suppliers have a secure online method to submit hearing requests. Now that hearing requests can be submitted online, it will be apparent to all parties when the request for a hearing is submitted, as the date on which the request was received by the CBIC was not apparent to suppliers in the past. Furthermore, this revision aligns with language used throughout § 414.423.

We solicited public comments on these amendments. We received comments in support of our CHOW proposal to remove the 60-day requirement and require submission of the novation agreement within 10 days of the effective date of the CHOW. We did not receive any comments on our other proposals for CHOWs or on our proposal for submission of a hearing request in a notice of a breach of contract appeal. We are finalizing our DMEPOS CBP proposals without change.

VIII. Requests for Information

A. Data Collection

1. Technical Expert Panel on Improving the Reporting of Composite Rate Costs under the ESRD PPS

a. Background

As we discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38396 through 38400), a Technical Expert Panel (TEP) was held on December 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. CMS contracted with a data contractor to convene this TEP and conduct research and analysis to refine the case-mix adjustment model. This TEP represented the first step in acquiring stakeholder and expert input to inform these refinements. The final TEP report and other materials can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/ESRDpayment/Educational_Resources.html.

The TEP was comprised of 16 expert stakeholders, including ESRD facilities, representatives of professional associations, independent academic clinical researchers, and patient advocates. In addition, a select number of observers attended, including representatives of governmental agencies and independent policy advisory groups. The TEP was organized into seven sessions, including an overview of the ESRD PPS and the cost components of dialysis treatment, four topical sessions corresponding to potential data collection strategies, and a final summary session.

b. Summary of the Data Contractor's Presentation to the TEP

i. Components of Dialysis Treatment Costs and Limitations of Current Data Collection

The data contractor's pre-TEP analysis of CY 2016 cost report data showed that composite rate costs comprise nearly 90 percent of average total treatment costs, with capital, direct patient care labor, and administrative costs representing approximately 88 percent of total average composite rate cost per treatment. Nevertheless, under current reporting practices, there are no data on the patient- and treatment-level variation in the cost of composite rate items and services. These findings underscore the importance of identifying variation in these costs to inform the development of a refined case-mix adjustment model.

ii. Data Collection Options

The data contractor presented the participants in the TEP with several options for optimizing data collection on composite rate items and services, and each option was specifically formulated to minimize reporting burden for ESRD facilities where possible. Feedback on these options and input on alternative approaches, as provided by the participants, would be used to further develop practical approaches for more accurate data collection.

Among the options presented for optimizing the collection of composite rate cost data were (1) improving the accuracy of charges and/or itemizing the use of composite rate services on claims; (2) reporting duration of each dialysis treatment session on claims (3) identifying and allocating costs to discrete categories of patients or patient characteristics that are associated with high cost of treatment; and (4) improving the reporting of facility-level costs. Each of these options is described in the following sections. The TEP participants' responses to these approaches are summarized in the Key Findings section at the end of this section. We note that our summary of the key findings is based on a review of the individual comments and is not meant to represent a consensus view shared by all TEP participants, but rather to consolidate related suggestions made by one or more participant.

iii. Improving the Accuracy of Charges

The data contractor presented two approaches for directly collecting data on the utilization of composite rate items and services. The first was to require more accurate reporting of charges for each dialysis session. Recent analysis of charge data revealed little variation in charges for any given revenue center code associated with a dialysis treatment, indicating that facilities are using standardized charges. The second approach was to require itemized reporting of all or a limited number of high cost composite rate items and services. Beginning in 2015[44], ESRD facilities were required to report selected composite rate services that were included on the Consolidated Billing List (CBL), however, the data contractor's analysis of reporting on use of these items showed that compliance has been minimal. Participants noted that these two options would be burdensome for ESRD facilities.

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44 Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978. December 2, 2014 (pp 3-4). https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf.

iv. Collection of Data on Duration of Dialysis Treatment

A singular option that would provide sufficient data to develop a refined case-mix adjustment model is the collection of dialysis treatment duration for each session. If dialysis session time were reported for each dialysis treatment, cost report and treatment-level data could be integrated to infer differences in composite rate costs across patients. In this paradigm, patient-level differences in composite rate costs could be attributed to two discrete categories: differences due to dialysis treatment duration (measured in units of time) and differences unrelated to treatment duration. Treatment duration would not be used to directly adjust payment, rather, it would be used to apportion composite rate costs that are currently only observable at the facility level to the patient or treatment level for use in the case-mix adjustment. Data on the duration of dialysis session would allow for a proportionately higher proportion of composite rate costs to be allocated to patients with longer dialysis treatment times.

The data contractor provided examples of ways that longer duration of dialysis time might be associated with increased treatment costs, including utility costs, accelerated depreciation on equipment, and lower daily census counts, which, among other things, would result in increased per-treatment capital costs. Additional labor hours for a patient with longer treatments on average could increase per-treatment labor costs, and patients with increased use of dialysate and water treatment supplies or equipment likely have higher average per-treatment supply costs.

The data contractor proposed two approaches to collect treatment duration data: (1) use existing data from Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) on delivered dialysis minutes during the monthly session when a laboratory specimen is drawn to measure blood urea nitrogen (BUN) or (2) have ESRD facilities report treatment duration on

Medicare claims. For the latter, treatment duration data could be reported by using a new HCPCS or revenue center code to indicate units of treatment time for each dialysis treatment or by updating the definition of the existing revenue center code for dialysis treatments so that the units correspond to treatment time instead of the number of treatments. ESRD facilities already report to CMS a single monthly treatment time in CROWNWeb for in-facility treatments, indicating that facilities currently collect treatment duration.[45] Moreover, many ESRD facilities' electronic health records (EHR) systems automatically collect this information for every dialysis treatment, minimizing additional burden of reporting this metric on claims.

v. Capturing Variation in Costs Associated with Complex Patients

Participants on the TEP also discussed the variation in composite rate costs that is independent of treatment duration and associated with severity of illness or disability in the dialysis patient population. In preparation for the TEP, the data contractor interviewed a number of ESRD facilities to identify sources of composite rate cost variation associated with the provision of care to more complex patients. Patient level-factors identified during the course of these interviews and during the TEP included seven points: (1) maintenance of isolation rooms and use of dedicated nurses to attend patients with active hepatitis B infection; (2) treatment and care for incident dialysis patients (first 120 days); (3) treatment and care for catheterized patients; (4) pre- and post-dialysis session care for non-ambulatory patients; (5) treatment and care for pediatric patients; (6) treatment of patients exhibiting behavioral problems related to mental illness/drug dependency; and (7) treatment and care for home dialysis patients.

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45 Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Payment Year (PY) 2021 Measure Technical Specifications. Page 23. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2021-Technical-Specifications-.pdf.

During the TEP, participants identified additional factors associated with higher treatment costs. These included hemodynamic instability, dual eligibility for Medicare and Medicaid, depression or mental illness, poor functional status, no primary caregiver, and institutionalized status or incarcerated or residence in a skilled nursing facility.

A common thread among these factors is that they all require more intense use of labor, especially direct patient care staff and highly specialized nursing or social work care or other intervention, such as would be provided by staff to assist in transfer for non-ambulatory patients.

The data contractor described alternative approaches for collecting sufficient data on these composite rate costs to inform a refined case-mix adjustment model. The first would entail reporting such items and services as line items on the claim. The second would involve grouping patients into a set of "high-risk" or "high-cost" patient types, in a hierarchical fashion and apportioning costs to each patient grouping based on known use of services.

vi. Facility-Level Costs

The TEP also included discussion of facility-level costs, identifying drivers of these costs, and the ESRD facility characteristics that may result in cost differences across facility types and potential revisions to the cost reports to better capture these costs. Participants on the TEP indicated that drivers of facility-level costs include: (1) facility size (treatment volume and treatment capacity), which affects economies of scale; (2) geographic location, which affects both input prices and wages; (3) hospital versus freestanding status; (4) ownership type; and (5) whether the facility offers specialized services, such as pediatric or home dialysis treatment. These facility characteristics can affect both capital and labor costs, as well as the costs for drugs, laboratory tests and supplies.

c. Key Findings

Based on a review of the individual participant responses to each of the data collection options, CMS has summarized key conclusions in the following sections. The sections are arranged in the order of the topical sessions, as they were presented earlier.

i. Components of Dialysis Treatment Costs and Limitations of Current Data Collection

During this session, the participants agreed that capital, labor, and administrative costs make up the majority of composite rate costs. They stated that the level of complexity of dialysis patients has been increasing over time, and noted some costs at the margins (for example, information technology costs) that are not reflected in cost reports. Participants were averse to reporting individualized charges to reflect treatment-level variation in the items and services provided, unless this reporting was somehow linked to payment.

ii. Duration of Dialysis Treatment

To record time on dialysis, participants preferred that the data be collected on Medicare claims. They did not support using existing CROWNWeb data on treatment duration, as there were too many questions about its completeness and timeliness. They agreed that if duration of dialysis treatment time is collected on claims that it should be reported in actual minutes dialyzed and not, for example, in 15-minute increments. The participants cautioned that reporting time on dialysis on the claims would place additional burden on facilities, but for facilities with EHRs, the burden associated with the collection of dialysis treatment time is expected to be small and temporary because the information is already collected. Collecting time on dialysis could be difficult to accomplish for ESRD facilities that do not use EHRs. Some participants maintained that certain factors related to patient complexity – such as comorbidities and mental health status – that are associated with treatment costs are unrelated to treatment duration.

iii. Identifying Costs Associated with Complex Patients

The participants expressed support for improving consistency in cost reporting across facilities. They recommended clarifying cost report instructions to ensure comparable reporting across facilities. They agreed that labor is the major source of patient-level cost variation, but expressed concern that allocating labor costs to the patient level or even the patient type would pose significant challenges. The participants noted that certain high-cost items and services used to treat complex patients, such as isolation rooms or lifts, could be easily itemized on claims and reported in cost reports. They proposed alternative approaches for quantifying resource use associated with complex patients, such as classifying resource use by intensity of care provided or tracking staff time across patients.

iv. Facility-level Costs

The participants stated that there are differences in cost at the facility level associated with the characteristics presented in the Facility-level Drivers of Cost session. They noted EHR practices are also associated with variation in facility-level cost. In addition, they emphasized that treatment volume relative to capacity has a significant financial impact on dialysis facilities; however, these costs currently are not reflected in cost reports. They also suggested that it might be beneficial to reflect missed treatments through a capacity utilization measure on the cost report and this could distinguish between more costly missed treatments and less costly planned absences, as the latter can be adjusted so that the facility chair is filled. The participants also indicated that rural facilities have costs not incurred by non-rural facilities, even among facilities with similar treatment volume, and do not believe the low volume payment adjustment and rural adjuster to be redundant.

d. Summary

This TEP focused on data collection on composite rate costs to inform the development

of a more refined case-mix adjustment model for the ESRD PPS. Currently two equations are used to calculate the base rate for payment: (1) one at the facility level and, (2) one at the patient or treatment level – because items in the composite rate are not collected at the patient level.[46]

While formerly separately billable items and services are itemized at the treatment level on claims and also reflected in cost reports, composite rate services, which comprise the bulk of the total costs for dialysis treatment are not itemized and can only be estimated at the facility level from cost reports. Charges for these services, as reported on claims, show little variation across facilities and cannot be used for estimating patient- or treatment-level variation in cost. Solutions for optimizing data collection on individual use of composite rate services were proposed by the data contractor and discussed by the participants. CMS' current goal, as emphasized throughout the TEP, is to explore options to improve the identification of per-treatment composite rate costs, and we invite comment on all of the options proposed during this TEP and discussed as part of this comment solicitation. We agree with the participants on the TEP that the benefits of improving the ESRD PPS case-mix adjustment model must be weighed against any additional ESRD facility burden that could result from changes to claims and cost reporting.

e. Solicitation for Input and Comment: Improving Data Collection on Composite Rate Costs

In the CY 2020 ESRD PPS proposed rule (84 FR 38398), CMS solicited input on options for improving the reporting of composite rate costs for the ESRD PPS. We explained that we believed improved reporting of both patient level costs, as reported on claims, and facility level costs, as reported on cost reports, is needed in order to obtain sufficient, high quality data to

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46 Medicare Claims Processing Manual. Chapter 8 – Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims. (Rev. 4202, 01-18-19). Page 7/143.

inform a refined case mix adjusted model for the ESRD PPS. We solicited comments on, or elaborations of, the options presented and discussed during the TEP, described in the CY 2020 ESRD PPS proposed rule (84 FR 38396) and also in section VIII.A.1.b.ii of this final rule, as well as novel approaches for improving the reporting of patient-level and facility-level costs that are not described here. We stated that CMS will consider new input from stakeholders as we develop methodologies for implementing select changes to claims and cost reports that serve to elucidate composite rate costs. We noted that CMS has not endorsed any particular method or option at this time.

i. Input Sought on Identifying Components of Composite Rate Costs

During the TEP, the data contractor identified six cost components comprising composite rate costs for the ESRD PPS. These include: (1) capital, (2) administrative, (3) labor, (4) drug, (5) laboratory and, (6) supply costs. Options were presented to improve the precision and accuracy of reporting costs for each component. Data on costs of some components, including capital, administrative and labor, are found chiefly in facility cost reports and reflect spending at the facility level. These facility-level costs, in combination with treatment counts can be used to estimate patient or treatment level composite rate costs. Data on other cost components, including drugs, laboratory tests and supplies, can be found both on the cost reports and on claims, however composite rate laboratory and supply costs are not specified on the cost report. Basic treatment charges are seen to vary little across patients or across facilities. Cost report data were questioned by the participants with regard to their accuracy and reliability.

Therefore, in the CY 2020 ESRD PPS proposed rule (84 FR 38398 through 38399), CMS solicited further input on ways to improve (1) the accuracy of charges and (2) the precision and reliability with which cost composite rate costs are identified and reported in cost reports.

We invited commenters to submit their responses to the following questions and requests:

- Do the six cost components include all aspects of dialysis treatment costs covered by Medicare?

  ++If not, please describe any further component costs within each component?

  ++Within each component, are there significant costs that are not currently captured in cost reports?
- The data contractor found that most composite rate costs are embedded in the capital, administrative and labor components. Given the relatively small contribution of drugs, laboratory tests, and supplies to composite rate costs, is there a justification for any further consideration of composite rate costs from capital, labor and administrative components?
- Why is there such limited variation in reported charges? Would it be useful to focus on improving reporting of these charges instead of collecting new information on cost reports or claims? Why is there such limited reporting of costs for items and services included in the CBL? Are there subsets of composite rate items and services that could be successfully reported on claims?

ii. Input Sought on Collection of Duration of Treatment Data

During the TEP, the data contractor proposed a paradigm by which to consider select changes to cost reporting that would reveal patient-level variation in costs, differentiating costs by those which can be attributed to dialysis treatment duration and those unrelated to treatment duration. Capturing data on these two types of differences was the thrust of the discussion during much of the TEP. In the CY 2020 ESRD PPS proposed rule (84 FR 38399), CMS solicited further input on these two elements of cost differential.

Dialysis session duration data could be used to refine calculations of per-treatment costs

by increasing specificity in the allocation of composite rate costs. Applying this change only to current data collection practices would suffice to account for treatment level differences in costs due to length of treatment. Duration data would allow for the distribution of composite rate component costs in such a way that a higher proportion of a facility's composite rate costs could be attributed to patients with longer dialysis treatment times. This would improve the precision with which costs for the use of such composite rate items and services as capital equipment use, water treatment and dialysate are allocated.

We invited comments on the option of collecting duration of treatments data, including responses to the following questions:

- Which of the six composite rate cost components (capital, administrative, labor, drug, laboratory, and supply costs) are most likely to vary with treatment duration?
- Should new information for these cost components be collected on cost reports, for use in better inferring the composite rate costs associated with treatment duration? If yes, please describe the additional information that would be needed and how this information could be used.
- Describe any challenges that would be encountered by ESRD facilities in reporting treatment duration, using a line item corresponding to units of time as a new revenue center code on the claim.
- Describe any alternatives to the use of dialysis treatment duration that could be used as a proxy for intensity of resource utilization and which can be reported at the patient/treatment level.

- Do facilities record the total time the patient spends in the facility before and after the actual dialysis treatment time, as well as the duration of the actual dialysis treatment? If so, please describe any obstacles to reporting this information on the claim.

iii. Input Sought on Collection of Data to Identify Sources of Variation in Treatment Costs Associated with Complex Patients

The data contractor presented a list of conditions, identified during pre-TEP interviews with ESRD facilities, associated with higher cost treatment for dialysis patients. During the TEP, the participants added to this list. The combined list of these conditions was described in the CY 2020 ESRD PPS proposed rule (84 FR 38397) and in section VIII.A.1.b.v of this final rule.

The data contractor also presented alternative approaches for collecting sufficient data on these composite rate costs so as to inform a refined case-mix model. One approach would entail reporting such items and services as line items on the claim. The second would involve grouping patients into a set of "high risk" or "high cost" patient types, in a hierarchical fashion, and apportioning costs to each patient grouping based on known use of services. There was no consensus among participants with regard to the best way to capture these costs.

In the CY 2020 ESRD PPS proposed rule (84 FR 38399), CMS solicited comments and suggestions about how to best capture these costs. In the proposed rule we provided the following questions to consider: First, to the extent labor is the dominant source of variation in cost in providing dialysis services to complex patients, please describe the amount and type of labor required to care for patients with the conditions described above or any other conditions which complicate the provision of basic dialysis treatment. Second, please describe other dimensions of dialysis care and treatment for which composite rate costs vary independent of

treatment duration. Third, are there discrete, high-cost composite rate items and services that vary at the patient level that could be feasibly itemized on claims? Fourth, how could a set of mutually exclusive, exhaustive patient groups be constructed to incorporate patients with common patterns of resource use? Fifth, what challenges might be faced in implementing the proposed reporting solutions a) on claims and b) on cost reports? Sixth, are pediatric and home dialysis costs accurately apportioned across cost components in cost reports? If not, please describe.

iv. Input Sought on Collection of Facility-level Data

During the TEP the data contractor presented a framework for considering facility-level drivers of cost, which meet two criteria: (i) they are independent of patient-level factors, and (ii) they affect the cost of dialysis treatment. The TEP debated each criterion for facility-level cost drivers, including facility size and realized treatment capacity. Geographic location affects wages and prices of goods and services. While some commenters have suggested that rural ESRD facilities incur higher costs, the data contractor's analysis of 2016 cost report data for the December 2018 TEP indicates that overall composite rate costs for rural facilities may be lower than for urban facilities. Further analysis by cost component suggests that with the exception of drug costs, urban facilities incur higher costs for each composite rate cost component. Ownership and other organizational factors, such as whether the facility administers a home dialysis program or serves the pediatric population also have a bearing on cost.

In the CY 2020 ESRD PPS proposed rule (84 FR 38399 through 38400), CMS solicited input from stakeholders regarding the further identification of facility-level drivers of cost, especially those that affect the cost of composite rate services. We asked commenters to consider the following questions: First, what facility level factors should be added or further

specified in the cost report to better reflect actual facility costs for the provision of composite rate items and services? Second, what are costs incurred by pediatric dialysis units that do not vary at the patient-level? Third, what types of costs do facilities providing home dialysis services incur that do not vary at the patient-level? Fourth, how do variations in drivers of facility costs affect composite rate costs at the facility level? Fifth, to what extent are these composite rate costs outside the facility's control? Sixth, what are the challenges or barriers to reporting missed treatments on claims and/or cost reports?

v. Other Input Needed

In the CY 2020 ESRD PPS proposed rule (84 FR 38400), we also solicited responses to the following questions that arose during the TEP. We noted that answers to these questions from the stakeholder community will help us to develop and refine reporting options for composite rate costs.

Beginning January 1, 2015, ESRD facilities have been required to itemize on claims the use of composite rate drugs listed on the CBL.[47] As presented at the TEP, the data contractor's analysis of 2016 claims data revealed that approximately 40 percent of facilities were not reporting these items. We requested that commenters identify any obstacles that might be preventing ESRD facilities from reporting the use of these composite rate drugs. Also, are there any drugs listed in the most recent CBL that are particularly challenging to report? If there are, please describe those challenges.

The participants mentioned that Medicare Advantage and other secondary payers will sometimes reject claims that include billing for certain items and services, such as oral

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47 Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978. December 2, 2014 (pp 3-4). https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf.

medications. We requested comments on the specific billing practices that lead to such claims being rejected, along with the specific items and services that are rejected by payers.

The participants expressed reservations about the reliability of cost report data and also about the comparability of cost reports between freestanding and hospital-based ESRD facilities.

We also solicited comments regarding suggested specific changes to the cost reports or cost report instructions that would be most useful to improve the consistency of reporting across facilities.

We received extensive comments on these issues from approximately 9 stakeholders and an additional 35 comments that indirectly addressed the request for information (RFI) for data collection. Below we provide a short synopsis of the findings for each of the topics discussed in the TEP and solicited for comment in the CY 2020 ESRD PPS proposed rule. We will provide a more detailed summary of the comments received on this RFI on the CMS website https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html. 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 detailed and thoughtful comments. We will consider these recommendations for future rulemaking.

Refinements to the Components of Composite Rate Costs

Some commentators expressed the opinion that use of composite rate components to price the cost of dialysis treatment was outmoded and counter to the objective of the bundled system instituted with the ESRD PPS in 2011. Although the RFI directed stakeholders to consider and comment on improving data collection for the determination of composite rate (CR) costs, the CR was not at the heart of their concerns. In fact, some commenters stated that the CR

was an outmoded and unnecessary concept, dating back to the time before the implementation of the ESRD PPS in 2011, and attempts to discern individual cost components of the CR essentially served to "unbundle" the PPS. However, there was general support for improved reporting of patient level costs on claims and facility level costs on cost reports.

Several commenters objected to CMS' continued use of the two-equation payment model. They claimed the two equation model is flawed insofar as it uses facility level regression analysis of cost report data to determine the cost per treatment for CR services and the results from patient level regression analysis from data derived from claims to determine the average payment per patient for drugs, laboratory services and supplies. Multiplying factors from each regression model "with different bases" diminishes the accuracy of the model.

Little Variation Found in Charges

Commenters claimed that charges for individual treatments were hard, if not impossible, to capture and that doing so would represent an undue burden for facilities.

CMS' contractor analyzed charges for basic dialysis services, as they are reported on claims, and found little variation in charges either across patients within facilities or across facilities. Stakeholders were asked to comment on this phenomenon and provide explanation. Commenters responded by stating that variations in charges are inconsistent and [their occurrence is non-systematic] making it difficult to focus on assessing charges for the purposes of itemizing composite rate costs. Examples were provided for items and services that could vary by treatment, but which would be difficult to capture in charges. These included nurse training and the difficulty of separating nurse training hours from other hours worked. Others commented that it is not possible to assess specific items to include in charges for each dialysis treatment.

Patient-level factors contributing to higher costs

With regard to patient-level factors contributing to high costs of care, commenters opined that patient-level adjusters should be based on sound, empirical evidence of their contribution to cost of care. There was general agreement that adjustments for the use of isolation rooms for patients with active HBV infection and for patients in their initial months of dialysis treatment were warranted. Commenters opposed the use of dialysis treatment duration maintaining that other factors were more directly related to cost of treatment.

Commenters expressed the opinion that the cost report data was an inappropriate source from which to derive accurate patient-level adjusters from aggregated facility data, such as is recorded in the cost reports.

Commenters also asked to eliminate or significantly revise the current case mix adjusters. Commenters repeatedly expressed concerns that the methodology that was used to derive the case mix adjusters was flawed and not empirically based. Some commenters recommended the elimination of all the current case mix adjusters. Others suggested revisions, including removal of some adjusters. Some stated that case mix adjusters were not necessary and that they defeated the purpose of the bundled payment, effectively unbundling it. Others believed that the use of multiple adjusters that were highly correlated was problematic.

Another objection to the use of too many patient level adjusters related to the difficulty of obtaining accurate comorbidity data. Commenters stated that these diagnoses are made by medical providers, not by ESRD facility staff, and are contained in medical records which are not readily accessible by the ESRD facility. They claimed that the operational costs of claiming comorbidity payment adjustment exceeded the value of the adjustment.

In particular the use of age, BMI, and BSA was challenged. Commenters stated that

there was no correlation between these factors and cost of dialysis treatment. Some commenters supported the use of patient-level cost factors that were presented at the 2019 TEP, including use of a catheter, non-ambulatory status, and some combined measure indicating behavioral, drug addiction or mental health problems, while others did not. Commenters endorsed the use of isolation rooms for patients with active HBV infection and an adjustment for patients in their initial period of dialysis.

The proposed use of duration of dialysis treatment time as a single, patient-level factor to estimate variation in CR costs was opposed. There was some indication that commenters thought that this method was being proposed in lieu of taking into account factors unrelated to treatment duration that made some patients more expensive to treat. Some commenters voiced the objection that use of this measure would not be productive because there was great homogeneity in treatment times across patients. Other commenters claimed that many subgroups of patients are challenged to stay on dialysis for the prescribed treatment time because of their physical status or other limitations, leading to more frequent treatment and/or higher costs and that these higher costs are related to patients' special circumstances and comorbidities and not to treatment duration.

Facility Level Adjusters and Suggested Changes to Cost Reports

With regard to facility-level factors driving costs, commenters agreed that the LVPA and rural adjustments needed refinement. They also were in agreement in calling for ESRD network fees and all bad debt to be added to cost reports as revenue reductions. Finally there was generally agreement that cost reports needed revisions to improve accuracy and consistency of reporting.

Commenters agreed that current cost reports omit several key cost components and that

more could be done to clarify reporting requirements in the cost report instructions. In particular, the ESRD network fee and bad debt were mentioned by several stakeholders as factors missing from the cost reports. Virtually all commenters who addressed this issue urged the inclusion of the ESRD network fee as a revenue reduction in Worksheet D of the cost report. They claimed that facilities were losing millions of dollars in reimbursable costs due to the omission of the ESRD network fee.

Bad debt was another facility-level cost that commenters strongly believed should be included in the cost report. Bad debt was characterized by contractors as pervasive problem that results when beneficiaries who face financial challenges cannot meet their cost sharing obligations. Presently, CMS only reimburses for 65 percent of bad debt liability (or 98 percent of 65 percent, if sequestration is taken into account). Commenters requested that 100 percent of bad debt be reimbursed. Commenters expressed that this problem will be exacerbated as new, more expensive treatments and devices come on the market. Commenters expressed the opinion that omission of unrecoverable bad debt results in a distorted representation of ESRD facility economics.

Several stakeholders also suggested that other revenue reductions should be allowed on the cost reports, including costs related to the ESRD QIP and losses related to budget sequestration. Finally, commenters requested that the cap on reporting of administrative salaries be removed.

The Low Volume Payment Adjuster (LVPA) and the Rural Adjuster were mentioned by several commenters as being problematic. First, some commenters expressed the opinion that the two adjusters were “overlapping” and suggested that a single, tiered low volume and “isolated facility” adjusters would serve better to target supplemental payments where they were

most needed. Others commented that the LVPA should be targeted at small and independent facilities, whose treatment costs were higher, rather than go to large dialysis organizations which are better able to absorb any excess costs in isolated less populated facilities and whose treatment costs in such facilities were lower than those incurred by independent facilities.

Home dialysis costs were mentioned by commenters as representing a cost component that has risen significantly in recent years. Commenters maintained that current allocation for facility level costs for home dialysis is not adequate due to higher costs for supplies and equipment and limited competition among vendors. Commenters stated that exacerbating this problem are training costs for the more highly skilled nurses required to train and attend to home dialysis beneficiaries, as well as survey and certification requirements.

Finally, hospital and freestanding facility costs are seen by commenters to be vastly different with hospitals incurring higher costs due to a "more intensive cost structure and/or clinically complex patient population" compared to freestanding facilities. Additionally higher costs may be an artifact of the peculiar structure of the hospital based ESRD cost report. Commenters suggested that revisions be made to correct data reporting and structural problems in the cost report. Commenters also expressed support for more granular reporting of costs in cost reports.

Reporting of Composite Rate Items on the Consolidated Billing List

Commenters expressed that the lack of availability of HCPCS codes for oral drugs prevent their reporting on claims.

Stakeholders were asked to comment on why so few facilities reported on the use of composite rate drugs that appeared on the Consolidated Billing List, as has been required since 2015. Responders stated that many oral medications do not have HCPCS codes that would allow

them to be itemized on claims and if claims are submitted to Medicare Advantage, including these items, the entire claim is rejected. Please see the Billing Practices section below for a further explanation of the consequences faced when such items are included on claims.

Billing Problems and Medicare Advantage

Commenters stated that Medicare Advantage and some other secondary payers rejected claims if they included certain items, including oral medications which did not have a HCPCS code.

Commenters mentioned several problems with Medicare Advantage (MA) billing practices for dialysis services. They stated that some MA plans will reject certain claims for a variety of reasons. Commenters reiterated the case made by panelists at the 2019 TEP that claims would be rejected by Medicare Advantage and other secondary payers if they contained certain drugs, including those that do not have HCPCS codes, as mentioned above, and in certain cases will not make separate payment to facilities for their provision of the TDAPA-eligible drugs. Commenters also stated that Medicare Advantage plans will reject claims that include more than 13 treatments per month, even when medically justified. This includes both in-center and home dialysis treatments. Commenters claimed that these practices discourage providers from offering home dialysis as a treatment option because of substantial increases in supply costs in recent years. Commenters also mentioned that MA plans often reject claims for dialysis treatments for beneficiaries traveling outside of the plan's network, having the unintentional result of restricting beneficiaries' ability to travel. Finally, commenters noted that Medicare Advantage plans do not always pay applicable payment adjustments for patients whose care otherwise is eligible for such adjustments. For example, MA plans do not always provide for the additional costs attendant to caring for patients in their first months of dialysis treatment, nor for

the extra care required for patients with complex comorbidities.

Special Consideration: Pediatric Dialysis Facilities

Commenters highlighted that pediatric dialysis facilities are a special case, that a pediatric case mix adjuster is warranted, and that significant revisions to cost reports should be made to allow for the true cost of providing care to this special population to be adequately reported.

The 2019 ESRD PPS TEP identified treatment and care for pediatric patients as a source of composite rate cost variation associated with providing care to more complex patients and called for further input on those costs. In response to the RFI, commenters itemized exceptional costs that were incurred by pediatric dialysis facilities, including the need for specialized staff, such as behavioral specialists, school liaisons and child life specialists. Additional expenses include a broad array of supplies and devices to accommodate a range of patient sizes. Commenters recommended that in addition to a pediatric case mix adjuster, CMS consider the additional capital and labor costs associated with pediatric patients and use these to formulate a more robust pediatric ESRD facility payment formula. Finally, they suggested that CMS consider alternative billing practices for pediatric facilities. They stated that these facilities are usually housed in children's hospitals which do not have experience with Medicare billing and reporting and lack the infrastructure to bill or provide required data accordingly.

B. Wage Index Comment Solicitation

As discussed in the CY 2020 ESRD PPS proposed rule (84 FR 38359 through 38360) and in section II.B.5.b of this final rule, historically, we have calculated the ESRD PPS wage index values using unadjusted wage index values from another provider setting. Stakeholders have frequently commented on certain aspects of the ESRD PPS wage index values and their impact

on payments. In the CY 2020 ESRD PPS proposed rule (84 FR 38400), we solicited comments on concerns stakeholders may have regarding the wage index used to adjust the labor-related portion of the ESRD PPS base rate and suggestions for possible updates and improvements to the geographic wage index payment adjustment under the ESRD PPS.

We received comments on this topic from approximately 6 stakeholders. Below we provide summaries of the comments received in response to the solicitation in the CY 2020 proposed rule. 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 detailed and thoughtful comments. We will consider these recommendations for future rulemaking.

Several commenters addressed the impact of data lag issues that they believe undermine the accuracy of the ESRD PPS wage indices. Under the current wage index methodology, CMS applies the most recent pre-floor, pre- classified hospital wage data collected annually under the Hospital IPPS. While commenters generally continue to support the methodology for determining the wage indices and the continued application of the wage index floor, they asked that CMS consider how the current policy could be modified to adjust wage index values to take into account laws requiring wage increases. They expressed that the wage index calculation data lag is particularly troublesome given higher wages due to state and municipality minimum wage actions and overall economic growth. They asserted that the current methodology will not capture these wage increases until years after their effect. They also noted that wage indices that do not reflect ESRD facilities' actual, current experience or the labor resources necessary to fulfill obligations under the Five-Star Quality Rating System and QIP will devalue the labor-related portion of the ESRD PPS base rate and inappropriately constrain ESRD PPS payments.

Commenters noted that under the current methodology, there can be a several year lag

with the wage index recognizing these changes. They urged CMS to work to minimize the data lag and ensure the expeditious incorporation of current state and municipality minimum wage requirements and overall labor market trends that influence labor costs into the wage indices' calculation.

One healthcare organization commented on CMS' proposal, in section II.B.5.b of the CY 2020 ESRD PPS proposed rule, to continue to use the pre-floor, pre-reclassified hospital wage index for ESRD services in CY 2020. The healthcare organization said that it understood that, until CMS is able to develop a wage index system for ESRD, CMS will need to use a proxy such as the hospital wage index. However, the organization does not agree with using the pre reclassified wage index values. Hospitals are regularly allowed to reclassify to higher wage index areas which results in higher payment rates. Because ESRD providers compete with local hospitals for staff, the payment differentials allow hospitals to offer higher compensation than can be maintained in a nonhospital setting. As a result, the healthcare organization stated, other providers such as ESRD facilities are at a disadvantage when competing for nursing staff. Rather than contributing to the disparities between facilities, the healthcare organization recommended that CMS equalize the wage index rates between hospitals and ESRD providers that utilize the hospital wage index by using the post floor, post-reclassification wage index for each CBSA.

A national dialysis association stated that CMS should not apply any wage index changes associated with the IPPS final rule without undergoing notice-and-comment rulemaking in an ESRD PPS proposed rule. The association explained that the wage index promulgated in the IPPS impacts the base rate for the ESRD PPS since the labor-related portion of the ESRD PPS base rate is adjusted to account for geographic differences in the area wage levels. The

association noted that the ESRD wage-index is based on the hospital index and utilizes pre-floor hospital data that are unadjusted for occupational mix. In addition to the hospital wage index being a critical component of the ESRD PPS base rate calculation, it also influences some of the facility-level adjusters, including the low-volume payment adjustment and the rural adjustment.

A professional association requested that CMS consider any such wage index changes in connection with any potential broad refinements to the ESRD PPS. The professional association recommended using a similar approach as the RFI for Data Collection because experiences of its members indicate that cost of care varies most by the patient's individual characteristics, comorbidities and psychosocial factors – as well as the relative severity of those individual comorbidities and psychosocial factors.

The association also noted that small and independent ESRD facilities typically have higher labor costs than larger dialysis organizations because of the generally higher proportion of skilled labor used in care delivery. The association urged CMS to formally recognize in the ESRD PPS the disproportionately higher labor costs borne by small and independent facilities as it considers possible changes to the ESRD PPS wage index.

The association also expressed that rural regions tend to experience higher labor costs than facilities in non-rural areas due to their difficulty in attracting labor. It noted that challenges in attracting qualified labor to care for the highly vulnerable ESRD patient population in rural areas are particularly acute given the overall shortage of nursing supply available and such issues have become even more critical with respect to attracting registered nurses and other clinical staff with experience in the provision of home dialysis – an expertise clearly sought after with the Administration's important initiatives to increase rates of home dialysis in ESRD treatment. Moreover, the association stated, if rural facilities are not able to find permanent staff locally,

they must pay the associated travel costs and wages for travel time for staff traveling from units outside of the area qualified to treat patients. The association noted that these staffing challenges raise labor costs for rural providers, increasing their overall costs to provide high-quality care for patients. The association therefore asked CMS to formally account for the additional financial burden rural providers face in securing qualified labor to meet ESRD patient care needs in any changes considered for the ESRD PPS wage index.

The association further suggested that as CMS considers possible changes to the ESRD PPS wage index, CMS examines how and why these two approaches of calculating the labor-related share have varied over time. The association stated that such examination may provide useful information about the specific approach to measurement and/or quality of the underlying data under either method, and could offer useful insights about the implications for the cost-side data sources utilized for any potential refinement to the ESRD PPS.

C. Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries (Section 50414 of the Bipartisan Budget Act of 2018)

1. Background

Section 1847(a)(2)(A) of the Act mandates competitive bidding programs for "covered items" and supplies used in conjunction with DME such as blood glucose monitors used by beneficiaries with diabetes. The supplies used with these blood glucose monitors (such as blood glucose test strips and lancets) are referred to under the DMEPOS CBP as diabetic supplies or diabetic testing supplies. In the April 10, 2007 final rule published in the **Federal Register** titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (72 FR 17992), which implemented the DMEPOS CBP, we established regulations to implement competitions on a

regional or national level for certain items such as diabetic testing supplies that are furnished on a mail order basis. We explained our rationale for establishing a national DMEPOS CBP for items furnished on a mail order basis in the May 1, 2006 proposed rule published in the **Federal Register** titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (71 FR 25669) and in the April 2007 final rule (72 FR 18018).

On January 16, 2009, we published an interim final rule in the **Federal Register** titled "Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)" that implemented certain changes to the DMEPOS CBP (74 FR 2873). Specifically, the rule implemented section 154 of MIPPA (Pub. L. 110-275), which delayed implementation of Round One of the program, required CMS to conduct a second Round One competition in 2009, and mandated certain changes for both the Round One Rebid and subsequent rounds of the program. In the January 2009 interim final rule, we indicated that we would be considering alternatives for competition of diabetic testing supplies in future notice and comment rulemaking.

On July 13, 2010 we published a proposed rule in the **Federal Register** titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 40211), in which we discussed alternatives for competition of diabetic testing supplies and proposed the implementation of a revised national mail order CBP for diabetic testing supplies. Under the proposed mail order DMEPOS CBP, we would award contracts to suppliers to furnish these items across the nation to beneficiaries who elect to have replacement diabetic testing supplies delivered to their residence. Suppliers wishing to furnish these items

through the mail to Medicare beneficiaries would be required to submit bids to participate in the national mail order CBP for diabetic testing supplies.

Section 154(d) of MIPPA modified section 1847(b)(10) of the Act to prohibit CMS from awarding a contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of all types of diabetes test strips on the market. With respect to any competition for diabetic testing strips after the first round of competition, a supplier must demonstrate that its bid to furnish diabetic testing strips covers the types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover at least 50 percent of all such types of products on the market. CMS and the CBIC refer to this rule as the "50 percent rule."[48] Section 1847(a)(10)(A) of the Act also specified that the volume for the different products may be determined in accordance with data (which may include market based data) recognized by the Secretary.

Section 1847(b)(10)(B) of the Act mandated that the Office of Inspector General (OIG) conduct a study before 2011 to determine the types of diabetic testing strips by volume that could be used by CMS for the purpose of evaluating bidders in the national mail order CBP for diabetic testing supplies. Under the DMEPOS CBP, bidding suppliers are required to provide information on the products they plan to furnish if awarded a contract. We proposed in the July 2010 proposed rule (75 FR 40211) to use information submitted by bidding suppliers and information on the market share (volume) of the various diabetic testing strip products to educate suppliers on meeting the requirements of this special 50 percent rule. We noted that it may be necessary to obtain additional information from suppliers such as invoices or purchase orders to verify that the requirements in the statute have been met (75 FR 40214). We proposed that

48 https://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf/$FIle/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf.

suppliers be required to demonstrate that their bids cover the minimum 50-percent threshold provided in the statute, but we invited comments on whether a higher threshold should be used (75 FR 40214). We proposed the 50 percent threshold in part because we believed that all suppliers have an inherent incentive to furnish a wide variety of types of diabetic testing products to generate a wider customer referral base (75 FR 40214). The 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top-selling diabetic test strip products (75 FR 40214). In addition, we proposed an "anti-switching provision" that we said would obviate the need to establish a threshold of greater than 50 percent for the purpose of implementing this special rule because the contract suppliers would not be able to carry a limited variety of products and switch beneficiaries to those products (75 FR 40214). For purposes of implementing the special rule in section 1847(b)(10)(A) of the Act, we proposed to define "diabetic testing strip product" as a specific brand and model of test strip, as we said that was the best way to distinguish among different products (75 FR 40214). Therefore, we planned to use market based data for specific brands and models of diabetic test strips to determine the relative market share or volume of the various products on the market that are available to Medicare beneficiaries (75 FR 40214). We stated we would apply this rule to non-mail order competitions and/or local competitions conducted for diabetic testing strips after Round One of the DMEPOS CBP (75 FR 40214).

In the November 29, 2010 final rule with comment period published in the **Federal Register** titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 73567), we established requirements for the national mail order CBP for diabetic testing supplies. We finalized the proposed special 50 percent rule mandated by section 1847(b)(10)(A) of the Act (75 FR 73611). We finalized our

proposal to require each bidder in the national mail order CBP for diabetic testing supplies to demonstrate that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products (75 FR 73611). We stated that the 50 percent threshold would ensure that beneficiaries have access to mail order delivery of the top selling diabetic test strip products from every contract supplier, and we adopted the 50 percent rule because we believed this was reflective of what suppliers were currently doing and ensured appropriate access for beneficiaries (75 FR 73611). We also stated that the OIG was conducting a study to generate volume data for various diabetic testing strip products furnished on a mail order basis (75 FR 73572). We stated that we would use this data as guidance to implement this special rule for mail order contract suppliers and ensure that their bids cover at least 50 percent of the volume of testing strip products currently furnished to beneficiaries via mail order (75 FR 73572). The OIG was required to complete their study before 2011 and we said we would make their data available to the public (75 FR 73572).

The OIG released its study in 2010, and the OIG has since determined the market shares of the types of diabetes test strips before each round of competitive bidding. The data from this series of reports informs CMS about the types of diabetes test strips that suppliers provide to Medicare beneficiaries via mail order.

Current Issues

The Bipartisan Budget Act of 2018 (BBA) was enacted on February 9, 2018, and section 50414 of the BBA amended section 1847(b)(10)(A) of the Act to establish additional rules for the competition for diabetic testing strips. Section 1847(b)(10)(A) of the Act now requires that for bids to furnish diabetic testing strips on or after January 1, 2019, the volume for such

products be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

The OIG reports to CMS the Medicare Part B market share of mail order diabetic test strips before each round of the Medicare national mail order CBP, and pursuant to section 1847(b)(10)(A) of the Act, the OIG will now report on the non-mail order diabetic test strip Medicare Part B market. On January 19, 2019, the OIG released a report that documented the Medicare Part B market share of mail order diabetic test strips for the 3-month period of April through June 2018.[49] On March 19, 2019, the OIG released another report that documented the Medicare Part B market share of non-mail-order diabetic test strip for the same 3-month period.[50] These data briefs represent OIG's third round of diabetic test strip Medicare market share reports since 2010, but this is the first series of reports that includes non-mail-order diabetic test strip data.

Because section 1847(b)(10)(A) of the Act now requires the use of "multiple sources of data," we requested public comments on other potential sources of data (sources other than the OIG), that fulfill the data requirements set forth in section 1847(b)(10)(A) of the Act. We requested comments on other potential sources of data because the word "multiple" in the phrase "multiple sources of data" could mean that we should use more than one source of data, and that the OIG is one source of data. We therefore requested comments from the public on other potential sources of data regarding the mail order and non-mail order Medicare markets for diabetic testing strips through this request for information. In particular, we sought data that:

- Has a sufficient sample size, and is unbiased and credible;

49 https://oig.hhs.gov/oei/reports/oei-04-18-00440.pdf.
50 https://oig.hhs.gov/oei/reports/oei-04-18-00441.pdf.

- Separately provides the market shares of the mail-order Medicare Part B market, and the non-mail order Medicare Part B market (does not combine the two markets into one); and
- Includes market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

We received 6 comments from suppliers, industry representative groups, and others in response to this Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries. Of the comments we received, none included data, or readily available sources of data, and were otherwise outside the scope of the request for information.

The comments received in response to the Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries are set forth below.

A few commenters recommended that CMS require suppliers to bill as they do for Medicare Part D. The commenters said that Part D billing allows for on-line claim adjudication, requiring that suppliers bill with a National Drug Code (NDC) product number so CMS can collect that data (the commenter recognized that there may be Paperwork Reduction Act issues). The commenters said that any survey of current Medicare Part B claims for diabetic testing strips would not accurately represent the overall market because reduced payment rates have caused suppliers to offer beneficiaries fewer product options. The commenters went on to say that the challenge with requesting this utilization information from manufacturers is that manufacturers do not know who will be paying for the product, and that manufacturer sales data is therefore not representative of products provided to Medicare beneficiaries.

One commenter said that CMS should only consider data for brands obtained under Medicare Part B, and that CMS should not consider diabetic testing supplies obtained through Part C or D because many of the supplies provided under Part C or Part D are on the formulary of the private insurance company. The commenter also stated that providers in the previous national mail order CBP did not have contracts with certain test strip manufacturers, as these manufacturers shut out the mail order providers in an attempt to drive patients to a pharmacy where they were able to work within the pharmacy benefit manager rebate programs. Another commenter said that information about access to certain test strip brands are potentially inaccurate, because some brands only contracted with certain national mail order CBP providers.

We appreciate the range of the comments we received. We will consider these comments carefully as we contemplate future policies.

IX. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. We solicited comments in the proposed rule, which published in the **Federal Register** on August 6, 2019 (84 FR 38330 through 38421). 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 requests.

B. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text. 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 wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purpose of the data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. The mean hourly wage of a Medical Records and Health Information Technician is $21.16 per hour.[51] Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $42.32 as the basis of the wage estimates for all collections 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 this updated wage estimate, along with updated facility and patient counts as well as a refined estimate of the time spent completing data entry for reporting data, to

51 https://www.bls.gov/oes/current/oes292071.htm

re-estimate the total information collection burden in the ESRD QIP for PY 2022 that we discussed in the CY 2019 ESRD QIP final rule (83 FR 57050 through 57052) and to estimate the total information collection burden in the ESRD QIP for PY 2023. We provide the re-estimated information collection burden associated with the PY 2022 ESRD QIP and the newly estimated information collection burden associated with the PY 2023 ESRD QIP in sections IV.C.2 and IV.C.3 of this final rule.

2. Estimated Burden Associated with the Data Validation Requirements for PY 2022 and PY 2023

In the CY 2019 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities would be selected each year to submit to CMS not more than 10 records, and we would reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimated that the aggregate cost of the CROWNWeb data validation each year will be approximately $30,885 (750 hours × $41.18), or an annual total of approximately $103 ($30,885/300 facilities) per facility in the sample. In this final rule, we are updating these estimates using a newly available wage estimate of a Medical Records and Health Information Technician and have made no other changes to our methodology for calculating the annual burden associated with the CROWNWeb validation study. 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 would submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately $31,740 (750 hours x $42.32), or an annual total of approximately $105.80 ($31,740/300 facilities) per facility in the sample. The increase in our burden estimate is due to an updated wage estimate for Medical Records and Health Information Technicians or similar staff and is not the result of any policies finalized in this final rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-1289).

In section IV.D.5 of this final rule, we are finalizing that we will continue in PY 2023 and subsequent payment years the NHSN data validation study using the methodology finalized in the CY 2019 ERD PPS final rule for PY 2022 (83 FR 57001 through 57002) and adopt the NHSN validation study as a permanent feature of the ESRD QIP. Under this methodology, we will select 300 facilities for participation in the PY 2023 validation study. A CMS contractor will send these facilities requests for 20 patients' records for each of the first 2 quarters of CY 2021 (for a total of 40 patient records per facility). The burden associated with these data validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. Using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that it will take each facility approximately 10 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 3,000 hours (300 facilities x 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff will submit these data, we estimate that the aggregate cost of the NHSN data validation each year

will be approximately $126,960 (3,000 hours × $42.32), or a total of approximately $423.20 ($126,960/300 facilities) per facility in the sample. The increase in our burden estimate is due to an updated wage estimate for Medical Records and Health Information Technicians or similar staff and is not the result of any policies finalized in this final rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-1340).

3. CROWNWeb Reporting Requirements for PY 2022 and PY 2023

To determine the burden associated with the CROWNWeb reporting requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In the CY 2019 ESRD PPS final rule, we estimated that the burden associated CROWNWeb reporting requirements for the PY 2022 ESRD QIP was approximately $202 million. We did not propose in the CY 2020 ESRD PPS proposed rule any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2022 or PY 2023. However, we re-calculated the burden estimate for PY 2022 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. In the CY 2019 ESRD PPS final rule, we estimated that the amount of time required to submit measure data to CROWNWeb was 2.5 minutes per element and used a rounded estimate of 0.042 hours in our calculations. In the proposed rule and in this final rule, we did not

use a rounded estimate of the time needed to complete data entry for CROWNWeb reporting. Based on the updated estimates that we used to re-calculate the burden estimate for PY 2022, we estimate that the PY 2022 burden is $211 million (or 4.8 million hours), and the net incremental burden from PY 2022 to PY 2023 is $0 (or 0 hours).

X. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically

significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicited comments on the regulatory impact analysis provided. With regard to the ESRD PPS, we did not receive any comments on the RIA.

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 2020. The finalized routine updates include the CY 2020 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to ESRD patients.

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 will result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services

furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule finalizes updates to the ESRD QIP, including a modification to the scoring methodology for the NHSN Dialysis Event reporting measure beginning with the PY 2022 ESRD QIP; the conversion of the STrR clinical measure to a reporting measure; and the adoption of the NHSN validation study as a permanent feature of the program using the methodology finalized for the PY 2022 NHSN validation study. In addition, we finalized that for all clinical measures in PY 2023 ESRD QIP, CY 2021 would be the performance period, CY 2020 would be the baseline period used to establish the improvement thresholds, and CY 2019 would be used for establishing the achievement thresholds, benchmarks, and minimum TPS. For future ESRD QIP payment years, we finalized that we would adopt automatically a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-filling)

This rule finalizes a gap-filling methodology for new DMEPOS items and services.

ii. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

This rule finalizes a method for making a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent within 5 years of establishing the initial fee schedule amounts.

e. Conditions of Payment to be Applied to Certain DMEPOS Items

This final rule will streamline the requirements for ordering DMEPOS items. It would also develop one Master List of DMEPOS items potentially subject to a face-to-face encounter,

written orders prior to delivery and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.

3. Overall Impact

a. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $210 million in payments to ESRD facilities in CY 2020, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and the change in the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent. These figures do not reflect estimated increases or decreases in expenditures based on the refinement to the TDAPA eligibility criteria, conditioning the TDAPA on ASP data availability, or providing the TPNIES. The fiscal impact of these policies cannot be determined due to the uniqueness of the new renal dialysis drugs and biological products and new renal dialysis equipment and supplies eligible for these add-on payment adjustments and their costs.

b. AKI

We are estimating approximately $40 million that will now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

c. ESRD QIP

For PY 2022, we have re-estimated the costs associated with information collection requirements under the Program with updated estimates of the total number of dialysis facilities, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. We have made no other changes to our methodology for

calculating the annual burden associated with the information collection requirements for with the CROWNWeb validation study, the NHSN validation study, and CROWNWeb reporting. None of the policies finalized in this final rule will affect our estimates of the annual burden associated with the Program's information collection requirements.

We also re-estimated the payment reductions under the ESRD QIP to correct an error in the way the weights were redistributed when estimating the PY 2022 payment reductions for the CY 2019 ESRD PPS final rule (83 FR 57060) and in accordance with the finalized policy changes described earlier, including the changes to the scoring methodology for the NHSN Dialysis Event reporting measure and the conversion of the STrR measure from a clinical measure to a reporting measure. We also updated the payment reduction estimates using newly available data for the PPPW clinical measure and the Ultrafiltration reporting measure and more recent data for the other measures in the ESRD QIP measure set. We estimate that these updates will result in an overall impact of $229 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule, which includes an estimated $211 million in information collection burden and an additional $18 million in estimated payment reductions across all facilities, for PY 2022.

For PY 2023, we estimate that the finalized revisions to the ESRD QIP will result in an overall impact of $229 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule, which includes an $18 million in estimated payment reductions across all facilities.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services

This final rule establishes a gap-filling methodology for new items and services. The

fiscal impact of the gap-filling methodology cannot be determined due to the uniqueness of potential new DMEPOS items and their costs.

ii. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

While these adjustments will decrease fee schedule amounts that have been established using supplier or commercial prices by less than 15 percent, the savings are considered a small offset to the potential increase in costs of establishing fee schedule amounts based on supplier invoices or prices from commercial payers. The fiscal impact for this provision is therefore considered negligible.

e. Conditions of Payment to be Applied to Certain DMEPOS Items

This rule finalizes to streamline the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

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 proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed comments on the approach in estimating the number of entities, which will review this final rule. We did not receive any comments on this section on the 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 on the rule.

Using the wage information from the Bureau of Labor Statistics (BLS) (https://www.bls.gov/oes/2018/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 $107,250. ($687.50 x 156 reviewers).

For manufacturers of DMEPOS products, DMEPOS suppliers, and other DMEPOS industry representatives, we calculate a different cost of reviewing this rule. Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review this final rule. For each entity that reviews this final rule, the estimated cost is $110.00. Therefore, we estimate that the total cost of reviewing this rule is $71,500 ($110.00× 650 reviewers).

B. Detailed Economic Analysis

1. CY 2020 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 2019 to estimated payments in CY 2020. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2019 and CY 2020 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 2018 data from the Part A and Part B Common Working Files as of September 18, 2019, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2018 claims to 2019 and 2020 using various updates. The updates to the ESRD PPS base rate are described in section II.B.5.d of this final rule. Table 14 shows the impact of the estimated CY 2020 ESRD payments compared to estimated payments to ESRD facilities in CY 2019.

TABLE 14: Impact of Finalized Changes in Payment to ESRD Facilities for CY 2020

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Effect of 2020 Changes in Outlier Policy (C)	Effect of 2020 Changes in Wage Index (D)	Effect of 2020 Changes in Payment Rate Update (E)	Effect of Changes in TDAPA (F)	Effect of Total 2020 Final Changes (G)
All Facilities	7,442	45.2	0.4%	0.0%	1.7%	-0.4%	1.6%
Type							
Freestanding	7,050	43.2	0.4%	0.0%	1.7%	-0.4%	1.6%
Hospital based	392	2.0	0.8%	0.0%	1.7%	-0.3%	2.1%
Ownership Type							
Large dialysis organization	5,698	35.1	0.4%	0.0%	1.7%	-0.4%	1.6%
Regional chain	930	5.7	0.4%	0.1%	1.7%	-0.5%	1.7%
Independent	502	2.9	0.4%	0.0%	1.7%	-0.4%	1.7%
Hospital based[1]	304	1.5	0.8%	0.0%	1.7%	-0.3%	2.2%
Unknown	8	0.0	1.3%	-0.8%	1.7%	-0.2%	2.1%
Geographic Location							
Rural	1,289	6.5	0.4%	0.1%	1.7%	-0.4%	1.8%
Urban	6,153	38.6	0.4%	0.0%	1.7%	-0.4%	1.6%
Census Region							
East North Central	1,195	6.2	0.4%	-0.2%	1.7%	-0.4%	1.5%
East South Central	589	3.3	0.4%	0.0%	1.7%	-0.5%	1.5%
Middle Atlantic	811	5.5	0.4%	-0.1%	1.7%	-0.4%	1.6%
Mountain	410	2.3	0.3%	0.0%	1.7%	-0.3%	1.7%
New England	198	1.4	0.4%	-0.5%	1.7%	-0.4%	1.2%
Pacific[2]	881	6.5	0.4%	0.5%	1.7%	-0.3%	2.2%
Puerto Rico and Virgin Islands	47	0.3	0.2%	-0.1%	1.7%	-0.3%	1.4%
South Atlantic	1,713	10.7	0.4%	-0.1%	1.7%	-0.5%	1.5%
West North Central	512	2.3	0.5%	0.3%	1.7%	-0.4%	2.1%
West South Central	1,086	6.6	0.4%	0.0%	1.7%	-0.5%	1.6%
Facility Size							
Less than 4,000 treatments	1,385	2.1	0.4%	0.0%	1.7%	-0.3%	1.8%
4,000 to 9,999 treatments	2,804	12.3	0.4%	0.0%	1.7%	-0.4%	1.7%
10,000 or more treatments	3,219	30.7	0.4%	0.0%	1.7%	-0.4%	1.6%

Unknown	34	0.1	0.4%	0.1%	1.7%	-0.6%	1.7%
Percentage of Pediatric Patients							
Less than 2%	7,338	44.8	0.4%	0.0%	1.7%	-0.4%	1.6%
Between 2% and 19%	41	0.3	0.5%	-0.1%	1.7%	-0.4%	1.7%
Between 20% and 49%	14	0.0	0.3%	0.0%	1.7%	-0.1%	1.9%
More than 50%	49	0.0	0.3%	-0.2%	1.7%	0.0%	1.8%

[1]Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2]Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.5.c of this final rule is shown in column C. For CY 2020, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.4 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2020 payments as a result of the final outlier policy changes.

Column D shows the effect of the final CY 2020 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.8 percent decrease to a 0.5 percent increase due to these final updates.

Column E shows the effect of the final CY 2020 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.7 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2020 of 2.0 percent and the final MFP adjustment of 0.3 percent.

Column F reflects the change in the payment of the TDAPA from ASP+6 percent to ASP+0 percent.

Column G reflects the overall impact, that is, the effects of the final outlier policy changes, the final wage index, payment rate update, and final TDAPA payment changes. We

expect that overall ESRD facilities would experience a 1.6 percent increase in estimated payments in CY 2020. The categories of types of facilities in the impact table show impacts ranging from an increase of 1.2 percent to 2.2 percent in their CY 2020 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 2020, we estimate that the final ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2020 would be approximately $10.3 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.4 percent in CY 2020.

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 final CY 2020 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2020, which translates to approximately $40 million.

e. Alternatives Considered

i. Eligibility criteria for the TDAPA

In section II.B.1 of this final rule, we finalized revisions to the drug designation process

regulation for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. In an effort to support innovation in the renal dialysis space, while simultaneously considering the cost to Medicare, for the refinement of the TDAPA eligibility we considered limiting it to only the Type 1 NDA Classification Code, section 351(a) biological products and section 351(k) biosimilar or interchangeable biological products. However, we wanted to support other innovative changes of drugs and biological products in the renal dialysis space and acknowledge that innovation may occur incrementally.

ii. New and innovative renal dialysis equipment and supplies under the ESRD PPS

In section II.B.3 of this final rule, we finalized to provide a transitional add-on payment adjustment to support the use of certain new and innovative renal dialysis equipment and supplies by ESRD facilities. With regard to pricing mechanisms for equipment and supplies, we considered alternatives such as those used in the DMEPOS program and consultation with the Pricing, Data, and Analysis Contractor. However, methodologies such as reasonable charges and use of fee schedules were lacking for many items and did not address the new and innovative renal dialysis equipment and supplies that we expect to be forthcoming with the KidneyX initiative.

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

a. Effects on ESRD Facilities

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 2019 to estimated payments in CY 2020. 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 2019 and CY 2020

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 2018 data from the Part A and Part B Common Working Files as of September 18, 2019, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2018 claims to 2019 and 2020 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 15 shows the impact of the estimated CY 2020 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 2019.

TABLE 15: Impact of Finalized Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2020

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of 2020 Changes in Wage Index (C)	Effect of 2020 Changes in Payment Rate Update (D)	Effect of Total 2020 Final Changes (E)
All Facilities	4,707	247.2	0.0%	1.7%	1.7%
Type					
Freestanding	4,585	243.1	0.0%	1.7%	1.7%
Hospital based	122	4.1	-0.1%	1.7%	1.6%
Ownership Type					
Large dialysis organization	3,934	209.1	0.0%	1.7%	1.7%
Regional chain	534	25.7	-0.1%	1.7%	1.6%
Independent	166	10.0	0.0%	1.7%	1.7%
Hospital based[1]	72	2.3	-0.1%	1.7%	1.6%
Unknown	1	0.0	0.5%	1.7%	2.2%
Geographic Location					
Rural	829	40.0	0.2%	1.7%	1.9%
Urban	3,878	207.2	0.0%	1.7%	1.7%
Census Region					
East North Central	849	47.2	-0.1%	1.7%	1.6%
East South Central	384	19.1	0.1%	1.7%	1.8%
Middle Atlantic	482	26.5	-0.3%	1.7%	1.4%
Mountain	283	15.8	-0.3%	1.7%	1.4%
New England	146	6.2	-0.6%	1.7%	1.1%
Pacific[2]	538	34.9	0.7%	1.7%	2.4%
Puerto Rico and Virgin Islands	2	0.0	0.0%	1.7%	1.7%
South Atlantic	1,097	56.1	-0.2%	1.7%	1.5%
West North Central	310	12.3	0.2%	1.7%	1.9%
West South Central	616	28.9	0.1%	1.7%	1.8%
Facility Size					
Less than 4,000 treatments	533	17.7	0.0%	1.7%	1.7%
4,000 to 9,999 treatments	1,875	90.9	0.0%	1.7%	1.7%
10,000 or more treatments	2,296	138.5	0.0%	1.7%	1.7%

Unknown	3	0.1	0.5%	1.7%	2.2%
Percentage of Pediatric Patients					
Less than 2%	4,706	247.2	0.0%	1.7%	1.7%
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	0.0	-1.8%	1.7%	-0.1%

[1]Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2]Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the final CY 2020 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 1.8 percent decrease to a 0.7 percent increase due to these final updates.

Column D shows the effect of the final CY 2020 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.7 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2020 of 2.0 percent and the final MFP adjustment of 0.3 percent.

Column E reflects the overall impact, that is, the effects of the final wage index and payment rate update. We expect that overall ESRD facilities would experience a 1.7 percent increase in estimated payments in CY 2020. The categories of types of facilities in the impact table show impacts ranging from a 0.1 percent decrease to a 2.4 percent increase in their CY 2020 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 and suppliers 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 update will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $40 million would be paid to ESRD facilities in CY 2020 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD

patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. We are finalizing in this final rule that we will convert the STrR clinical measure to a reporting measure, and also change the way the NHSN Dialysis Event reporting measure is scored. The general methodology that we are using to determine a facility's TPS is described in our regulations at § 413.178(d).[52]

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2022, as codified in our regulations at § 413.177.

For the PY 2022 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 26.1 percent or 1,871 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2022. The total payment reductions for all the 1,871 facilities expected to receive a payment reduction is approximately $18,247,083.76. Facilities that do not receive a TPS do not receive a payment reduction.

Table 16 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

[52] We are redesignating § 413.178(d) as § 413.178(e) in this final rule.

TABLE 16: Estimated Distribution of PY 2022 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,293	73.88%
0.5%	1,339	18.69%
1.0%	432	6.03%
1.5%	81	1.13%
2.0%	19	0.27%

*223 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2022, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 17) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 17. We also note that because we are finalizing in section IV.D.2.b of this final rule that we will convert the STrR measure from a clinical measure to a reporting measure, the STrR measure is no longer listed in Table 17.

TABLE 17: Data Used to Estimate PY 2022 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, medians (50th percentiles of the national performance), benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SHR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
%Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR, facilities were required to have at

least 5 at risk patients, 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.D of this final rule. Facility reporting measure scores were estimated using available data from CY 2018. Facilities were required to have at least one measure in at least two 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 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 18 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2022 ESRD QIP, the actual impact of the PY 2022 ESRD QIP may vary significantly from the values provided here.

TABLE 18: Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2022

	Number of Facilities	Number of Treatments 2018 (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	7,386	44.6	7,164	1,871	-0.17%
Facility Type:					
Freestanding	6,995	42.7	6,807	1,764	-0.17%
Hospital-based	391	1.9	357	107	-0.23%
Ownership Type:					
Large Dialysis	5,603	34.5	5,487	1,286	-0.15%
Regional Chain	927	5.7	897	264	-0.19%
Independent	512	2.9	490	227	-0.36%
Hospital-based (non-chain)	305	1.5	276	87	-0.25%
Unknown	39	0.0	14	7	-0.32%
Facility Size:					
Large Entities	6,530	40.2	6,384	1,550	-0.15%
Small Entities[1]	817	4.4	766	314	-0.32%
Unknown	39	0.0	14	7	-0.32%
Rural Status:					
1) Yes	1,285	6.5	1,242	158	-0.08%
2) No	6,101	38.2	5,922	1,713	-0.19%
Census Region:					
Northeast	1,004	6.9	976	250	-0.16%
Midwest	1,696	8.4	1,637	418	-0.17%
South	3,360	20.4	3,244	964	-0.20%
West	1,271	8.6	1,252	197	-0.09%
US Territories[2]	55	0.4	55	42	-0.51%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,141	329	-0.20%
East South Central	587	3.3	579	146	-0.16%
Middle Atlantic	806	5.4	781	221	-0.18%
Mountain	409	2.3	404	60	-0.10%
New England	198	1.4	195	29	-0.08%
Pacific	862	6.3	848	137	-0.09%
South Atlantic	1,699	10.5	1,650	536	-0.22%
West North Central	508	2.2	496	89	-0.11%
West South Central	1,074	6.6	1,015	282	-0.18%
US Territories[2]	47	0.3	47	40	-0.58%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,117	230	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	510	-0.12%
Over 10,000 treatments	3,159	29.8	3,149	1,019	-0.20%
Unknown	377	0.5	278	112	-0.37%

[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 2023 ESRD QIP on ESRD Facilities

For the PY 2023 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 26.1 percent or 1,871 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. The total payment reductions for all the 1,871 facilities expected to receive a payment reduction is approximately $18,247,083.76. Facilities that do not receive a TPS do not receive a payment reduction.

Table 19 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 19: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,293	73.88%
0.5%	1,339	18.69%
1.0%	432	6.03%
1.5%	81	1.13%
2.0%	19	0.27%

*223 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 19) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 20. We also note that because we are finalizing in section IV.D.2.b of this final rule that we will convert the STrR measure from a clinical measure to a reporting measure, the STrR measure is no longer listed in Table 20.

TABLE 20: Data Used to Estimate PY 2023 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
%Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR, facilities were required to have at least 5 at-risk patients, 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 policies finalized in section IV.D and IV.E of this final rule. Facility reporting measure scores were estimated using available data from CY 2018. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 21 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2023. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography

(both rural and urban and by region), and by facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period that we are finalizing to use for the PY 2023 ESRD QIP, the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided here.

TABLE 21: Impact of QIP Payment Reductions to ESRD Facilities for PY 2023

	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	7,386	44.6	7,164	1,871	-0.17%
Facility Type:					
Freestanding	6,995	42.7	6,807	1,764	-0.17%
Hospital-based	391	1.9	357	107	-0.23%
Ownership Type:					
Large Dialysis	5,603	34.5	5,487	1,286	-0.15%
Regional Chain	927	5.7	897	264	-0.19%
Independent	512	2.9	490	227	-0.36%
Hospital-based (non-chain)	305	1.5	276	87	-0.25%
Unknown	39	0.0	14	7	-0.32%
Facility Size:					
Large Entities	6,530	40.2	6,384	1,550	-0.15%
Small Entities[1]	817	4.4	766	314	-0.32%
Unknown	39	0.0	14	7	-0.32%
Rural Status:					
1) Yes	1,285	6.5	1,242	158	-0.08%
2) No	6,101	38.2	5,922	1,713	-0.19%
Census Region:					
Northeast	1,004	6.9	976	250	-0.16%
Midwest	1,696	8.4	1,637	418	-0.17%
South	3,360	20.4	3,244	964	-0.20%
West	1,271	8.6	1,252	197	-0.09%
US Territories[2]	55	0.4	55	42	-0.51%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,141	329	-0.20%
East South Central	587	3.3	579	146	-0.16%
Middle Atlantic	806	5.4	781	221	-0.18%
Mountain	409	2.3	404	60	-0.10%
New England	198	1.4	195	29	-0.08%
Pacific	862	6.3	848	137	-0.09%
South Atlantic	1,699	10.5	1,650	536	-0.22%
West North Central	508	2.2	496	89	-0.11%
West South Central	1,074	6.6	1,015	282	-0.18%
US Territories[2]	47	0.3	47	40	-0.58%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,117	230	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	510	-0.12%
Over 10,000 treatments	3,159	29.8	3,149	1,019	-0.20%
Unknown	377	0.5	278	112	-0.37%

[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 facilities, such as through the impacts of the Hospital Readmission 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 2023, we estimate that the ESRD QIP will contribute approximately $18,247,083.76 in Medicare savings. For comparison, Table 19 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2023. We note that Table 22 contains a lower estimated payment reduction for PY 2022 than we included in Table 49 of the CY 2019 ESRD PPS final rule (83 FR 57061).

TABLE 22: Estimated Payment Reductions Payment Years 2018 through 2023

Payment year	Estimated payment reductions
PY 2023	$18,247,083.76
PY 2022	$18,247,083.76
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

e. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on 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. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

f. Alternatives Considered

In response to the concern raised by commenters about the validity of the modified STrR measure, we considered aligning the STrR measure's specifications with those used for the measure prior to the PY 2021 ESRD QIP. However, that version of the STrR clinical measure was not endorsed by the NQF due to the concern expressed by the Renal Standing Committee about variability in hospital coding practices.

4. DMEPOS

a. Establishing Payment Amounts for New DMEPOS Items and Services (Gap-Filling)

(1) Effects on Other Providers

We believe that establishing payment amounts for new DMEPOS items and services will have a positive economic impact on suppliers by making the pricing of new items more easily understood and encourage innovation. The cost cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

This final rule has an indeterminable cost to the Medicare program associated with it due to the unpredictable nature of future new items.

(3) Effects on Medicare Beneficiaries

This final rule has an indeterminable cost to the Medicare beneficiary due to the unpredictable nature of future new items. This rule also has an indeterminable cost to the dual-eligible beneficiary who is enrolled in the Medicare and the Medicaid programs for the same reason as indicated above.

(4) Alternatives Considered

One alternative we considered but did not propose was to continue the process for establishing payment amounts for new items on a sub-regulatory basis. This would have no economic impact on the Medicare program or its beneficiaries.

b. Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices

(1) Effects on Other Providers

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices will have a negative economic impact on suppliers by lowering fees. The savings cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices will have a positive economic impact on the Medicare Program by lowering fees and achieving savings. The savings cannot be estimated as these new items are not identified.

(3) Effects on Medicare Beneficiaries

We believe that adjusting payment amounts for new DMEPOS items and services when initially set based on supplier or commercial prices will have a positive economic impact on Medicare beneficiaries by lowering fees, therefore resulting in lower coinsurance for such items. The savings cannot be estimated as these new items are not identified.

(4) Alternatives Considered

An alternative we considered but did not propose was to continue not adjusting payment amounts for new items based on revised supplier and commercial price lists. This would have resulted, in some cases, in what we consider to be fee schedule amounts that were too high and a cost to the program and beneficiaries.

5. Conditions of Payment to be Applied to Certain DMEPOS Items

This rule streamlines the requirements for ordering DMEPOS items, and to identify the process for subjecting certain DMEPOS items to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements as a condition of payment. The fiscal impact of these requirements cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

C. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 23, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 23: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI	
Category	**Transfers**
Annualized Monetized Transfers	$170 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$40 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2022	
Category	**Transfers**
Annualized Monetized Transfers	-$18 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2023	
Category	**Transfers**
Annualized Monetized Transfers	-$18 million
From Whom to Whom	Federal government to ESRD providers

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

D. 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 $41.5 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 https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.p

df) (Kidney Dialysis Centers are listed as 621492 with a size standard of $41.5 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 14. Using the definitions in this ownership category, we consider 502 facilities that are independent and 304 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 $41.5 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 ESRD facility) is estimated to receive a 2.2 percent increase in payments for CY 2020. An independent facility (as defined by ownership type) is estimated to receive a 1.7 percent increase in payments for CY 2020.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $40 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,871 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2023 ESRD QIP, 314 are ESRD

small entity facilities. We present these findings in Table 16 ("Estimated Distribution of PY 2023 ESRD QIP Payment Reductions") and Table 18 ("Impact of QIP Payment Reductions to ESRD Facilities for PY 2023"). We estimate that the payment reductions will average approximately $9,752.58 per facility across the 1,871 facilities receiving a payment reduction, and $9,288.57 for each small entity facility. We also estimate that there are 817 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities will decrease 0.32 percent in CY 2023.

The DMEPOS provisions in this final rule, Establishing Payment Amounts for New DMEPOS Items and Services and Gap-Filling and Adjusting Payment Amounts for DMEPOS Items and Services Gap-Filled Using Supplier or Commercial Prices in section V of this final rule, are not considered to have a significant impact on a number of small suppliers. We note that the fiscal impact of the Conditions of Payment to be applied to Certain DMEPOS Items in section VI of this final rule cannot be estimated as this rule only identifies all items that are potentially subject to the face-to-face encounter and written order prior to delivery requirements and/or prior authorization.

Therefore, the Secretary has determined that these final rules would not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

We solicited comment on the RFA analysis provided. We received no comments on this section.

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 would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 126 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 126 rural hospital-based dialysis facilities will experience an estimated 2.2 percent increase in payments.

Therefore, the Secretary has determined that these final rules would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. 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 2019, that threshold is approximately $154 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 $154 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.

F. 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, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. It has been determined that this is a transfer rule, which imposes no more than de minimis costs. As a result, this rule is not considered a regulatory or deregulatory action under Executive Order 13771.

H. 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.

XI. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and is posted on the CMS website at http://www.cms.gov/ESRDPayment/PAY/list.asp. In addition to the Addenda, limited data set files are available for purchase at http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html. Readers who experience any

problems accessing the Addenda or LDS files, should contact ESRDPayment@cms.hhs.gov.

List of Subjects

42 CFR Part 405

Federal health insurance for the aged and disabled, Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologicals, Drugs, Health facilities, Health professions, 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 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

2. Section 410.36 is amended by revising paragraph (b) to read as follows:

§ 410.36 Medical supplies, appliances, and devices: Scope.

* * * * *

(b) The conditions of payment described in § 410.38(d) also apply to medical supplies, appliances, and devices.

3. Section 410.38 is amended--

a. By revising the section heading;

b. By revising paragraph (a);

c. In paragraph (b) by adding a paragraph heading;

d. By revising paragraphs (c), (d), and (e); and

e. By removing paragraphs (f) and (g).

The revisions and addition read as follows:

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

(a) *General scope*. Medicare Part B pays for durable medical equipment, including ventilators, oxygen equipment, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) *Institutions that may not qualify as the patient's home*. * * *

(c) *Definitions*. As used in this section:

(1) *Physician* has the same meaning as in section 1861(r)(1) of the Act.

(2) *Treating practitioner* means physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

(3) *DMEPOS supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(4) *Written Order/Prescription* is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.

(5) *Face-to-face encounter* is an in-person or telehealth encounter between the treating practitioner and the beneficiary.

(6) *Power mobility device (PMD)* means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

(7) *Master List of DMEPOS items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, also referred to as "Master List,"* are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in § 414.234 of this chapter. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

(8) *Required Face-to-Face Encounter and Written Order Prior to Delivery List* is a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery. The list of items is published in the **Federal Register** and posted on the CMS website. The list is effective no less than 60 days following its publication. When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of Payment*. The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription*. All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements*. A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Order Date.

(E) Treating Practitioner Name or National Provider Identifier (NPI).

(F) Treating Practitioner Signature.

(ii) *Timing of the Written Order/Prescription.*

(A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items Requiring a Face-to-Face Encounter*. For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 of this chapter must be met.

(3) *Documentation*: A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements*. CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rulemaking, except those items for which inclusion on the Master List was statutorily imposed.

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

4. 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.

5. Section 413.178 is amended --

a. In paragraph (a)(4) by removing the reference "paragraphs (d)(1)(i) through (v)" and adding in its place the reference "paragraphs (e)(1)(i) through (v)";

b. In paragraph (a)(13) by removing the reference to "paragraph (d)(1)(vi) " and adding in its place the reference "paragraph (e)(1)(vi)";

c. By redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively;

d. By adding a new paragraph (d);

e. In newly redesignated paragraph (e)(2)(i) by removing the reference "paragraph (d)(1)" and adding in its place the reference "paragraph (e)(1)"; and

f. In newly redesignated paragraph (f)(2) by removing the cross-reference to "paragraph (e)(1)" and adding in its place "paragraph (f)(1)".

The revisions and additions read as follows:

§ 413.178 ESRD quality incentive program.

* * * * *

(d) *Data submission requirement.* (1) Except as provided in paragraph (d)(3) and (4) of this section, and for a payment year, facilities must submit to CMS data on each measure specified by CMS under paragraph (c) of this section. Facilities must submit these data in the form, manner, and at a time specified by CMS.

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to the 2023 payment year is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2020 for purposes of calculating the improvement threshold, and the performance period that applies to the 2023 payment year is calendar year 2021. Beginning with the 2024 payment year, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

(3) A facility may request and CMS may grant exceptions to the reporting requirements under paragraph (d)(1) of this section for one or more calendar days, when there are certain extraordinary circumstances beyond the control of the facility.

(4) A facility may request an exception within 90 days of the date that the extraordinary circumstances occurred by submitting the Extraordinary Circumstances Exception request form, which is available on the QualityNet web site (https://www.qualitynet.org/), to CMS via email to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Facilities must provide the following information on the form:

(i) Facility CCN.

(ii) Facility name.

(iii) CEO name and contact information.

(iv) Additional contact name and contact information.

(v) Reason for requesting an exception.

(vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

(5) CMS will not consider an exception request unless the facility requesting such exception has complied with the requirements in paragraph (d)(4) of this section.

(6) CMS may grant exceptions to facilities without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) An unresolved issue with a CMS data system affected the ability of a facility to submit data in accordance with paragraph (d)(1) of this section and CMS was unable to provide the facility with an alternative method of data submission.

(7) A facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at ESRDQIP@cms.hhs.gov. Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility.

* * * * *

6. Section 413.230 is amended by—

a. Revising paragraphs (b) and (c); and

b. Adding paragraph (d) and (e).

The revision and additions read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(b) Any outlier payment under § 413.237;

(c) Any training adjustment add-on under § 413.235(c);

(d) Any transitional drug add-on payment adjustment under § 413.234(c); and

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d).

7. Section 413.234, as previously amended on November 14, 2018, is further amended–

a. In paragraph (a) by revising the definitions of "ESRD PPS functional category" and "Oral only drug;"

b. By revising paragraph (b)(1)(ii);

c. By revising paragraph (c) introductory text; and

d. By adding paragraph (e).

The revisions and addition read as follows:

§ 413.234 Drug designation process.

(a) * * *

ESRD PPS functional category. A distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

* * * * *

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) * * *

(1) * * *

(ii) Except as provided in paragraph (e) of this section, 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.

* * * * *

(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). 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. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not

available.

* * * * *

(e) *Exclusion criteria for the transitional drug add-on payment adjustment.* A new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in paragraphs (e)(1) through (7) of this section, respectively:

(1) Type 3 NDA – New Dosage Form.

(i) A *Type 3 NDA* is for a new dosage form of an active ingredient that has been approved or marketed in the United States (U.S.) by the same or another applicant but in a different dosage form. The indication for the drug product does not need to be the same as that of the already marketed drug product. Once a new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as a *Type 5 NDA*, as described in paragraph (e)(2) of this section.

(ii) [Reserved]

(2) Type 5 NDA - New Formulation or Other Differences.

(i) A *Type 5 NDA* is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the following:

(A) The product involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and is submitted as an original NDA rather

than as a supplement by the applicant of the approved product;

(B) The product is a duplicate of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination), and

(1) Requires bioequivalence testing (including bioequivalence studies with clinical endpoints), but is not eligible for submission as a section 505(j) of the FD&C Act application; or

(2) Requires safety or effectiveness testing because of novel inactive ingredients; or

(3) Requires full safety or effectiveness testing because it is:

(i) Subject to exclusivity held by another applicant, or

(ii) A product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, or

(iii) A crude natural product, or

(iv) Ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability (for example, products with different release patterns); or

(4) The applicant has a right of reference to the application.

(C) The product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources.

(D) The product is a combination product that differs from a previously marketed combination by the removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one or more of the active ingredients. In the latter case, the NDA would be classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 5 NDA* as described in paragraph

(e)(2) of this section.

(E) The product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A *Type 5 NDA*, as described in paragraph (e)(2) of this section, would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

(F) The product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act.

(G) The product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, *Parenteral drug products in plastic containers*).

(ii) [Reserved]

(3) Type 7 NDA - Previously Marketed But Without an Approved NDA.

(i) A *Type 7 NDA* is for a drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the U.S. This classification applies only to the first NDA approved for a drug product containing this (these) active moiety(ies). *Type 7 NDAs* include, but are not limited to:

(A) The first post-1962 application for an active moiety marketed prior to 1938.

(B) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation notice. Regulation at 21 CFR 310.6(b)(1) states that an identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well

as any of drug moiety related in chemical structure or known pharmacological properties.

(C) The first application for an IRS drug product first marketed after 1962.

(D) The first application for an active moiety that was first marketed without an NDA after 1962.

(ii) [Reserved]

(4) Type 8 NDA - Prescription to Over-the-Counter (OTC).

(i) A *Type 8 NDA* is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription (OTC switch). A *Type 8 NDA* may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

(ii) If the proposed OTC switch will apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), the applicant should submit a new NDA for the OTC products, which would be classified as a *Type 8 NDA*.

(5) *Combination of Type 3 NDA*. Type 3 NDA, as described in paragraph (e)(1) of this section, in combination with a Type 2 NDA, as described in paragraph (e)(5)(i) of this section, or in combination with a Type 4 NDA, as described in paragraph (e)(5)(ii) of this section;

(i) Type 2 NDA – New Active Ingredient.

(A) A *Type 2 NDA* is for a drug product that contains a new active ingredient, but not a

new molecular entity (NME). A new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the unmodified parent molecule would also be considered a new active ingredient, but not an NME. The indication for the drug product does not need to be the same as that of the already marketed product containing the same active moiety.

(B) If the active ingredient is a single enantiomer and a racemic mixture containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a *Type 2 NDA*.

(ii) Type 4 NDA – New Combination.

(A) A *Type 4 NDA* is for a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient. The new product may be a physical or chemical (for example, covalent ester or noncovalent derivative) combination of two or more active moieties.

(B) A new *physical combination* may be two or more active ingredients combined into a single dosage form, or two or more drugs packaged together with combined labeling. When at least one of the active moieties is classified as an NME, the NDA is classified as a combination of a *Type 1 NDA*, as described in paragraph (e)(5)(ii)(B)(1) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section. When none of the active moieties is an NME,

but at least one is a new active ingredient, the NDA is classified as a combination of a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section.

(1) Type 1 NDA – New Molecular Entity.

(i) A *Type 1 NDA* is for a drug product that contains an NME. An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the FD&C Act or has been previously marketed as a drug in the U.S. A pure enantiomer or a racemic mixture is an NME only when neither has been previously approved or marketed.

(ii) An NDA for a drug product containing an active moiety that has been marketed as a drug in the U.S., but never approved in an application submitted under section 505 of the FD&C Act, would be considered a *Type 7 NDA* as described in paragraph (e)(3) of this section, not a *Type 1 NDA*.

(iii) An NDA for a drug-drug combination product containing an active moiety that is an NME in combination with another active moiety that had already been approved by FDA would be classified as a new combination containing an NME (that is, *Type 1,4 NDA*, as described in paragraph (e)(5)(ii) of this section). For example, a drug-drug combination can include a fixed-combination drug product or a co-packaged drug product with two or more active moieties.

(iv) An active moiety in a radiopharmaceutical (or radioactive drug product) which has not been approved by the FDA or marketed in the U.S. is classified as an NME.

(v) In addition, if a change in isotopic form results in an active moiety that has never been approved by the FDA or marketed in the U.S., the active ingredient is classified as an NME.

(C) An NDA for an active ingredient that is a *chemical combination* of two or more

previously approved or marketed active moieties that are linked by an ester bond is classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA* as described in paragraph (e)(5)(ii) of this section, if the active moieties have not been previously marketed or approved as a physical combination. If the physical combination has been previously marketed or approved, however, such a product would no longer be considered a *new* combination and the NDA would thus be classified as a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(6) *Combination of Type 5 NDA*. Type 5 NDA, as described in paragraph (e)(2) of this section, in combination with a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(7) *Type 9 NDA when the parent NDA is a Type 3, Type 5, Type 7, or a Type 8.* A *Type 9* NDA, as described in paragraph (e)(7)(i) of this section when the parent NDA is a *Type 3* NDA as described in paragraph (e)(1) of this section or a *Type 5* NDA as described in paragraph (e)(2) of this section or *Type 7* NDA as described in paragraph (e)(3) of this section or a *Type 8* NDA as described in paragraph (e)(4) of this section.

(i) Type 9 NDA - New Indication or Claim, Drug Not to be Marketed under Type 9 NDA after Approval.

(A) A *Type 9* NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the "parent NDA"), and the applicant does not intend to market this drug product under the *Type 9* NDA after approval. Generally, a *Type 9* NDA is submitted as a separate NDA so as to be in compliance with the guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*.

(B) When the *Type 9* NDA is submitted, it will be given the same NDA classification as

the pending NDA. When one application is approved, the other will be reclassified as *Type 9* regardless of whether it was the first or second NDA actually submitted. After the approval of a *Type 9* NDA, FDA will "administratively close" the *Type 9* NDA and thereafter only accept submissions to the "parent" NDA.

(ii) [Reserved]

* * * * *

8. Section 413.236 is added to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis*. This section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(b) *Eligibility criteria.* For dates of service occurring on or after January 1, 2020, CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under § 413.171;

(2) Is new, meaning it is granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020;

(3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;

(4) Has a Healthcare Common Procedure Coding System (HCPCS) application

submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance; and

(6) Is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications*. CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies*. A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.* (1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

9. Section 413.237 is amended by –

a. Revising paragraph (a)(1)(i) through (iv);

b. Redesignating paragraph (a)(1)(v) as paragraph (a)(1)(vi);

c. Adding new paragraph (a)(1)(v); and

d. Revising newly redesignated paragraph (a)(1)(vi).

The revisions and addition read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(i) Renal dialysis drugs and biological products that were or would have been, prior to

January 1, 2011, separately billable under Medicare Part B;

(ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and

(v) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

(vi) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

* * * * *

PART 414--PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

10. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

11. Section 414.110 is added to subpart C to read as follows:

§ 414.110 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General Rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

12. Section 414.112 is added to subpart C to read as follows:

§ 414.112 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for

comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI-U minus current CPI-U) divided by current CPI-U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in § 414.102(c).

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new supplier or commercial prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the deflation formula in paragraph (c)(1) of this section.

13. Section 414.234 is amended --

a. In paragraph (a) by adding the definition of "Required Prior Authorization List" in alphabetical order;

b. By revising the heading of paragraph (b) and revising paragraphs (b)(1), (b)(2), (b)(3)(i) through (b)(3)(iii), (b)(4), and (b)(6);

c. By revising paragraphs (c)(1)(i) and (ii);

d. By revising paragraphs (d)(1) introductory text and (d)(1)(i);

e. By revising paragraph (e)(3) and (4); and

f. By adding paragraph (e)(5).

The revisions and addition read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

(a) * * *

Required Prior Authorization List is a list of DMEPOS items selected from the Master List and subject to the requirements of prior authorization as a condition of payment.

* * * * *

(b) *Master List of Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements*.

(1) Master List Inclusion Criteria are as follows:

(i) Any DMEPOS items included in the DMEPOS Fee Schedule that have an average purchase fee of $500 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or an average monthly rental fee schedule of $50 (adjusted annually for inflation using consumer price index for all urban consumers (CPI-U), and reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period)) or greater, or are identified as accounting for at least 1.5 percent of Medicare expenditures for all DMEPOS items over a 12-month period that are:

(A) Identified as having a high rate of potential fraud or unnecessary utilization in an Office of Inspector General (OIG) or Government Accountability Office (GAO) report that is national in scope and published in 2015 or later, or

(B) Listed in the 2018 or later Comprehensive Error Rate Testing (CERT) Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report as having a high improper payment rate, or

(ii) The annual Master List updates shall include any items with at least 1,000 claims and 1 million dollars in payments during a recent 12-month period that are determined to have aberrant billing patterns and lack explanatory contributing factors (for example, new technology or coverage policies). Items with aberrant billing patterns would be identified as those items

with payments during a 12-month timeframe that exceed payments made during the preceding 12-months, by the greater of:

(A) Double the percent change of all DMEPOS claim payments for items that meet the above claim and payment criteria, from the preceding 12-month period, or

(B) Exceeding a 30 percent increase in payment, or

(iii) Any item statutorily requiring a face-to-face encounter, a written order prior to delivery, or prior authorization.

(2) The Master List is self-updating at a minimum annually, and is published in the **Federal Register.**

(3) * * *

(i) OIG reports published after 2020.

(ii) GAO reports published after 2020.

(iii) Listed in the CERT Medicare FFS Supplemental Improper Payment Data report(s) published after 2020 as having a high improper payment rate.

(4) Items are removed from the Master List after 10 years from the date the item was added to the Master List, unless the item was identified in an OIG report, GAO report, or having been identified in the CERT Medicare FFS Supplemental Improper Payment Data report as having a high improper payment rate, within the 5-year period preceding the anticipated date of expiration.

* * * * *

(6) An item is removed from the list if the cost drops below the payment threshold criteria set forth in paragraph (b)(1)(i) of this section.

* * * * *

(c) * * *

(1) * * *

(i) The Required Prior Authorization List specified in paragraph (c)(1) of this section is selected from the Master List. CMS may consider factors such as geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis and may implement prior authorization nationally or locally.

(ii) CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region. CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process.

* * * * *

(d) * * *

(1) Include all relevant documentation necessary to show that the item meets applicable Medicare coverage, coding, and payment rules, including those outlined in § 410.38 and all of the following:

(i) Written order/prescription.

* * * * *

(e) * * *

(3) If applicable Medicare coverage, coding, and payment rules are not met, CMS or its contractor issues a non-affirmation decision to the requester.

(4) If the requester receives a non-affirmation decision, the requester may resubmit a

prior authorization request before the item is furnished to the beneficiary and before the claim is submitted for processing.

(5) A prior authorization request for an expedited review must include documentation that shows that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function. If CMS or its contractor agrees that processing a prior authorization request using a standard timeline for review could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function, then CMS or its contractor expedites the review of the prior authorization request and communicates the decision following the receipt of all applicable Medicare required documentation.

* * * * *

14. Section 414.236 is added to subpart D to read as follows:

§ 414.236 Continuity of pricing when HCPCS codes are divided or combined.

(a) *General rule.* If a new HCPCS code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

(b) *Mapping fee schedule amounts based on different kinds of coding changes.* When the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the

single code continue to apply to each of the items described by the new codes. When the codes for the components of a single item are combined in a single global code, the fee schedule amounts for the new code are established by totaling the fee schedule amounts used for the components (that is, use the total of the fee schedule amounts for the components as the fee schedule amount for the global code). When the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes.

15. Section 414.238 is added to subpart D to read as follows:

§ 414.238 Establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

(a) *General rule.* If a HCPCS code is new and describes items and services that do not have a fee schedule pricing history (classified and paid for previously under a different code), the fee schedule amounts for the new code are established based on the process described in paragraphs (b) or (c) of this section.

(b) *Comparability.* Fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

(c) *Use of supplier or commercial price lists.* (1) Fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

(i) The annual deflation factors are specified in program instructions and are based on the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period, as calculated using the following formula: ((base CPI-U minus current CPI-U) divided by current CPI-U) plus one.

(ii) The deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME, section 1834(h)(4) of the Act for prosthetic devices, prosthetics, orthotics, and therapeutic shoes and inserts, and section 1834(i)(1)(B) of the Act for surgical dressings.

(2) If within 5 years of establishing fee schedule amounts using supplier or commercial prices, the prices decrease by less than 15 percent, a one-time adjustment to the fee schedule amounts is made using the new prices. The new prices would be used to establish the new fee schedule amounts in the same way that the older prices were used, including application of the

deflation formula in paragraph (c)(1) of this section.

16. Section 414.422 is amended by revising paragraph (d) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(d) *Change of ownership (CHOW)*. (1) CMS may transfer a contract to a successor entity that merges with, or acquires, a contract supplier if the successor entity--

(i) Meets all requirements applicable to contract suppliers for the applicable competitive bidding program;

(ii) Submits to CMS the documentation described under § 414.414(b) through (d) if documentation has not previously been submitted by the successor entity or if the documentation is no longer sufficient for CMS to make a financial determination. A successor entity is not required to duplicate previously submitted information if the previously submitted information is not needed to make a financial determination. This documentation must be submitted prior to the effective date of the CHOW; and

(iii) Submits to CMS a signed novation agreement acceptable to CMS stating that it assumes all obligations under the contract. This documentation must be submitted no later than 10 days after the effective date of the CHOW.

(2) Except as specified in paragraph (d)(3) of this section, CMS may transfer the entire contract, including all product categories and competitive bidding areas, to a successor entity.

(3) For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company (for example, a subsidiary) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a successor entity, if the following conditions are

met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the successor entity that meets all competitive bidding requirements; that is, financial, accreditation, and licensure;

(ii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iii) All requirements of paragraph (d)(1) of this section are met;

(iv) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(v) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

* * * * *

17. Section 414.423 is amended by revising paragraph (f)(2) to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

* * * * *

(f) * * *

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

*** * * * ***

Dated: October 24, 2019.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: October 28, 2019.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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