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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-P]

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 (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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2020. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This proposed rule also proposes to update requirements for the ESRD Quality Incentive Program (QIP). In addition, this rule proposes a methodology for calculating fee schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services and 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

proposes to revise existing regulations related to the competitive bidding program for DMEPOS. This proposed rule also would streamline the requirements for ordering DMEPOS items, and develop 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 proposed rule includes 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: To be assured consideration, comments must be submitted at one of the addresses provided below, no later than September 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS-1713-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1713-P,

P.O. Box 8010

Baltimore, MD 21244-8010.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1713-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT:

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

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

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

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

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

Maria Ciccanti, (410) 786-3107; and Emily Calvert, (410) 786-4277, for issues related to the DMEPOS written order, face-to-face encounter, and prior authorization requirements.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the

close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Table of Contents

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

I. Executive Summary

A. Purpose

This proposed rule contains proposals 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, DMEPOS Competitive Bidding Program (CBP) proposed amendments, 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 proposes updates and 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 proposes to update 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 proposed rule proposes several updates for the ESRD QIP.

4. DMEPOS Fee Schedule Payment Rules

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

This rule proposes to establish a gap-filling methodology in regulations for pricing new 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 proposes a one-time adjustment to the gap-filled fee schedule amounts in cases where prices decrease by less than 15 percent.

5. Conditions of Payment to be Applied to the Proposed Master List of DMEPOS Items

This proposed rule would 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.

B. Summary of the Major Provisions

1. ESRD PPS

- Update to the ESRD PPS base rate for CY 2020: The proposed CY 2020 ESRD PPS base rate is $240.27. This proposed 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 (1.004180), equaling $240.27 ($235.27 x 1.017 x 1.004180 = $240.27).

- Annual update to the wage index: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2020, we are proposing to update the wage index values based on the latest available data.

- Update to the outlier policy: We are proposing to update the outlier policy using the most current data, as well as update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2020 using CY 2018 claims data. Based on the use of the latest available data, the proposed FDL amount for pediatric beneficiaries would decrease from $57.14 to $44.91, and the MAP amount would decrease from $35.18 to $33.82, as compared to CY 2019 values. For adult beneficiaries, the proposed FDL amount would decrease from $65.11 to $52.50, and the MAP amount would decrease from $38.51 to $36.60. 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 would 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 proposing 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 proposing to exclude 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 NDA Types 3, 5, 7 and 8, Type 3 in combination with Type 2 or Type 4, 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.

- Proposal to change the basis of payment for the TDAPA for calcimimetics: We are continuing 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 are proposing to reduce 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. We believe that in paying the TDAPA for these products since 2018, we have provided sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. We also believe we need to take into account the financial burden that increased payments place on beneficiaries and Medicare expenditures.

- Average sales price (ASP) conditional policy for application of the TDAPA: Under the policy finalized in the CY 2019 ESRD PPS final rule, effective January 1, 2020, the basis of payment for the TDAPA for all new renal dialysis drugs and biological products

except calcimimetics 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 concerned that if ASP data is not available to CMS, WAC or invoice pricing would likely increase Medicare expenditures more than the value of the ASP. We are proposing 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 would 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 proposing 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. We believe it is important to balance supporting ESRD facilities in their uptake of innovative new renal dialysis drugs and biological products with limiting increases to Medicare expenditures, and conditioning the TDAPA on the availability of ASP data would help us achieve that balance.

- New and innovative renal dialysis equipment and supplies under the ESRD PPS:

We are proposing to pay a transitional add-on payment adjustment to support the use of certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities. We are proposing to include renal dialysis equipment and supplies (with the exception of capital-related assets) that are: (1) granted marketing authorization by FDA on or after January 1, 2020, (2) commercially available, (3) have a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official

Level II HCPCS coding procedures, and (4) meet the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at 42 CFR 412.87(b)(1). Specifically, under our proposal, the equipment or supply must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. CMS would evaluate the application to determine eligibility for a transitional add-on payment adjustment. We are proposing that the payment adjustment for these new and innovative renal dialysis equipment and supplies would 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 would pay the adjustment for 2-calendar years, after which the equipment or supply would qualify as an outlier service and no change to the ESRD PPS base rate would be made.

- Discontinue the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS: We are proposing to discontinue the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS. Prior to implementation of the ESRD PPS, ESAs were paid separately, which resulted in gross overutilization. We continued to apply the EMP edits when we implemented the ESRD PPS so that we did not overvalue these biological products in determining eligibility for outlier payments. Since we bundled ESAs into the per treatment payment amount, overutilization and the incentive for overutilization have been eliminated from the ESRD PPS; therefore we believe the EMP is no longer necessary.

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

We are proposing to update the AKI payment rate for CY 2020. The proposed CY

2020 payment rate is $240.27, which is the same as the base rate proposed under the ESRD PPS for CY 2020.

3. ESRD QIP

This proposed rule proposes several new requirements for the ESRD QIP beginning with payment year (PY) 2022, including but not limited to the following:

- Updates to the 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.
- A proposal to convert the STrR clinical measure (NQF #2979) to a reporting measure while we examine concerns raised by stakeholders regarding the measure's validity.

We are not proposing any new requirements beginning with the PY 2023 ESRD QIP.

We are also proposing to make updates to 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 proposes 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 proposed 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 proposes a one-time adjustment to the gap-filled fee schedule amounts. We are not proposing these price adjustments in cases where prices increase.

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

This proposed rule would 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.

C. Summary of Costs and Benefits

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

1. Impacts of the Proposed ESRD PPS

The impact chart in section XI of this proposed 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 proposed CY 2020 changes is projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.9 percent increase in payments compared with freestanding facilities with an estimated 1.5 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately $210 million in CY 2020 compared to CY 2019. This reflects a $230 million increase from the payment rate update and a $40 million increase due to the updates to the outlier threshold amounts, and a $60 million decrease from the proposal to change 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 our proposals to refine the TDAPA eligibility criteria, condition the TDAPA on the availability of ASP data, and provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies. The fiscal impact of these proposals cannot be determined because these new renal dialysis drugs and biological products and new renal dialysis equipment and supplies 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 would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2020, which translates to approximately $50 million.

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

The impact chart in section XI of this proposed rule displays the estimated change in proposed payments to ESRD facilities in CY 2020 compared to estimated payments in CY 2019. The overall impact of the proposed CY 2020 changes is projected to be a 1.7 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.8 percent increase in payments compared with freestanding facilities with an estimated 1.7 percent increase.

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

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the PY 2022 ESRD QIP would be approximately $219 million as a result of the policies we have previously finalized and the

proposals in this proposed rule. The $219 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate would be approximately $205 million. We also estimate that the overall economic impact of the PY 2023 ESRD QIP would be approximately $219 million as a result of the policies we have previously finalized. The $219 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate would be approximately $205 million.

4. Impacts of the Proposed DMEPOS Fee Schedule Payment Rules

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

This rule proposes 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 proposed 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 proposing 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 would 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 proposes 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 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 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 expanded the TDAPA policy. Effective January 1, 2020, the TDAPA is available for all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories.

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) (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, 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. Provisions of the Proposed Rule

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 intravenous products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration (FDA). Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). 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 intravenous product

is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or intravenous product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

In the CY 2016 ESRD PPS final rule, we also established in § 413.234(b)(2) that, if the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage. Next, the new injectable or intravenous product is paid for using the TDAPA described in § 413.234(c). Then, the new injectable or intravenous 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 intravenous product are available, but not for less than 2 years. During the time a new injectable or intravenous product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or intravenous 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 intravenous drugs and biological products in the ESRD

PPS bundled payment, such new products were the primary focus of the regulation we adopted at § 413.234. We 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, we finalized the expansion of the eligibility criteria for the TDAPA to reflect the proposed policy in the CY 2019 ESRD PPS final rule (83 FR 56943). In that rule we explained that there are two 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 provide an ability for 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, to be able to compete with higher priced drugs during the TDAPA period. In addition, 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 provides 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 believe 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 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 (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 Proposed Refinement of the TDAPA Eligibility Criteria

Based on feedback received during and after the CY 2019 ESRD PPS rulemaking, we are 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 proposed rule, we received many comments from all sectors of the dialysis industry and other stakeholders on our proposal 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. 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, commenters also had specific policy recommendations for each element of

the drug designation process, including which drugs should qualify for the TDAPA.

In the CY 2019 ESRD PPS final rule (83 FR 56938) some commenters recommended, among other suggestions, that CMS not apply the TDAPA to generic drugs or to biosimilar biological products. The 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. 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, a drug manufacturer commented 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). Further, 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. 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.

Some commenters recommended that CMS require that the new renal dialysis drug or biological product, in order to be eligible for the TDAPA, have a clinical superiority over existing drugs in the ESRD PPS bundled payment and provided suggestions on clinical value

criteria. 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 (83 FR 56938). A drug manufacturer recommended that CMS consider when FDA may re-profile a drug (83 FR 56939). The commenter further explained that re-profiling a drug may occur when its utility and efficacy are further elucidated or expanded once on-market. The commenter recommended that CMS establish a pathway as part of the drug designation process that would allow for manufacturers or other stakeholders to request that CMS reconsider how a particular drug is classified with regard to the functional categories.

MedPAC 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 (83 FR 56936). 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.

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.

Also, 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 this proposed rule. 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 new drug applications (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] Section 505 of the FD&C Act includes FDA approval of NDAs for drugs that have a new dosage form, a reformulation, or a re-engineering of an existing product. These types of drugs are referred to in the pharmaceutical industry as line extensions, follow-on products, or me-too drugs.

Due to the feedback received following publication of the CY 2019 ESRD PPS final rule, we continued to analyze certain aspects of the policies finalized in the CY 2019 ESRD PPS final rule and are revisiting these issues as part of this proposed 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 are 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.

As noted previously, 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

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

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." While there are several parts of this definition, in this proposed rule we are focusing 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 are proposing that certain new renal dialysis drugs approved by FDA under those authorities would not be eligible for the TDAPA under § 413.234(c)(1).

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). Therefore, 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 explained 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.

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. 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.

Section 505(b)(2) of the FD&C Act is another pathway for NDAs, but where at least some of the information for an approved drug 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 then subdivided into categories by FDA.

The Office of Pharmaceutical Quality in FDA's Center for Drug Evaluation and Research's (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 code 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. The NDA

classification code is not indicative of the extent of innovation or therapeutic value that a particular drug represents. More information regarding the NDA classification code 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
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

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. ANDAs are used for generic drugs. An ANDA relies on FDA's finding that the previously approved drug product, that is, the reference listed drug, is safe and effective.

Biological products are approved by FDA under section 351 of the PHS Act. There are two pathways for biological products, one under section 351(a) and the other under section 351(k) of the PHS Act. A BLA submitted under section 351(a) of the PHS Act is the pathway for "stand-alone BLAs" that contains all 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. FDA does not assign classification codes for BLAs like it does for NDAs.

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 have 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. This could cause an influx of non-innovative drugs to the dialysis space, potentially crowding out innovative drugs.

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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," that is, a previously approved drug product. See 54 FR 28872 (July 10, 1989).

c. Proposed Refinement of the TDAPA Eligibility Criteria

We analyzed the information we gathered since the publication of 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 continue to believe that this is accomplished by providing payment 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 continue to believe that the TDAPA provides additional payment for costs associated with these changes.

In addition to supporting innovation, we are mindful of the increase in Medicare expenditures associated with the expanded TDAPA policy. We note 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 were balancing an increase in Medicare expenditures with the rationale for fostering a competitive marketplace. In the CY 2019 ESRD PPS final rule (83 FR 56937), we stated that we believed that by expanding the eligibility 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.

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 are reconsidering the eligibility criteria that we finalized effective January 1, 2020. Since there are not unlimited Medicare resources, we believe those resources should not be expended on additional payments to ESRD facilities for drugs and biological products that are not truly innovative, and may facilitate perverse incentives for facilities to choose new products simply for financial gain. 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 believe that 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 acknowledge 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 acknowledge 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 acknowledge that while dialysis industry stakeholders recommended that we adopt significant clinical improvement standards for the TDAPA eligibility, we believe 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. 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. Further, 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. 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.

In section II.B.1.c.i of this proposed rule we discuss categories of drugs that we are proposing to exclude from eligibility for the TDAPA under § 413.234(b)(1)(ii) and our proposed revisions to the drug designation process regulation in § 413.234 to reflect those categories.

We are also proposing 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. The FDA/CDER MAPP 5018.2 is available at FDA website https://www.fda.gov/media/94381/download. We recognize 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 believe 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 believe 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.

As discussed in section II.B.1.b of this proposed rule, 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. If FDA makes changes to the NDA classification code in FDA/CDER MAPP 5018.2, we are proposing that 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 in the next rulemaking cycle, any necessary revisions to the exclusions set forth in proposed § 413.234(e). We are soliciting comment on the proposal to rely on, as a proxy, the NDA classification code, as it exists as of November 4, 2015, which is part of the FDA/CDER MAPP 5018.2. We are also soliciting comments on the proposal that we would assess FDA changes to the NDA classification code 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.

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. 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, 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.[3] If the FDA NDA Type classified 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 note that we plan to have quarterly meetings with FDA to

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

discuss new renal dialysis drugs and biological products that are eligible for the TDAPA.

As we discuss 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. 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.

For new renal dialysis drugs and biological products that are not eligible for the TDAPA, we indicated that a change request would be issued that will provide notice that the drug is included in the ESRD PPS bundle, qualifies as an outlier service, and is available for use, allowing patients to have access to the new product.

i. Proposed Exclusions from the TDAPA Eligibility

Using the current categories in FDA/CDER MAPP 5018.2 effective November 4, 2015, we are proposing 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(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 would use the NDA classification code Type identified at FDA approval. If FDA changes the classification type after we start applying the TDAPA with respect to a particular new renal dialysis drug, we would re-evaluate TDAPA eligibility. We are also proposing to exclude generic drugs from being eligible for the TDAPA under § 413.234(c)(1).

In the following paragraphs we describe each NDA Type, as distinguished by FDA through the NDA classification code, and generic drugs proposed for exclusion and explain why we believe 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

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 are proposing 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). In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d), when the "parent NDA" is a Type 3 NDA.

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).

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.

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.

For purposes of the ESRD PPS, we do not want to incentivize the use of one dosage form of the drug over another. In addition to not being innovative, these drugs that are new to the market may not be innovative with regard to certain characteristics of the drug itself. Although these drugs may provide an expansion of patient treatment options, we believe these changes are not innovative and these drugs should not be paid for using the TDAPA. However, these drugs are still accounted for in the ESRD PPS base rate and would be eligible for an outlier payment. This type of research, development and marketing activity has been termed "product hopping" and can help manufacturers prolong revenue streams.[4] We do not believe these products should be eligible for the TDAPA because we do not want to provide perverse incentives for facilities to choose a new dosage form in order to obtain the TDAPA. In addition, we do not want to encourage the practice of companies moving drug research and development dollars from one branded drug to another, very similar drug with a longer patent life, thus increasing its market exclusivity for many years. This practice is 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

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

payment for the utilization of high value, innovative drugs. For these reasons we are proposing to exclude Type 3 NDA drugs as being eligible for the TDAPA.

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

We are proposing to exclude Type 5 NDA drugs, which can be a new formulation or new manufacturer, from being eligible for the TDAPA. In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d) of this proposed rule, when the "parent NDA" is a Type 5 NDA. Drugs that are classified as a Type 5 NDA are sometimes referred to as reformulations or follow-on products. Specifically, 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. 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. 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. 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 would propose to exclude it from eligibility for the TDAPA under § 413.234(b)(1).

The fifth characteristic is that the product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A Type 5 NDA 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.

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).

Some commenters have characterized the types of drugs that are often approved in Type 5 NDAs as reformulations or line extensions. 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] 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 pharmaceutical company that makes the original product, or 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 proposed rule. 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 are 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

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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.

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

formulation and taking out new patents for the new formulation.[8] 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 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. While Type 5 NDA drugs may have clinical benefits to patients over previously approved products, we do not make that assessment as part of ESRD PPS payment policy. 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.[10] For these reasons, we do not believe that 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

In addition, 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] This and other recent publications

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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

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

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 believe it is 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 do not believe Type 5 NDA drugs should be eligible for the TDAPA, and we are proposing to exclude them in new § 413.234(e).

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

We are proposing to exclude Type 7 NDA, which 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., from being eligible for the TDAPA for renal dialysis drugs and biological products in existing functional categories. In addition, we are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d) of this proposed rule, when the "parent NDA" is a Type 7 NDA. 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 do not believe that 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. This drug is not innovative and does not significantly advance the treatment options for ESRD. 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 was one of the goals of the TDAPA. In addition, 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 do not consider Type 7 NDA drugs to be eligible for the TDAPA.

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

We are proposing 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 are proposing to exclude Type 9 NDAs, as discussed in section II.B.1.ii.(d) of this proposed rule, when the "parent NDA" is a Type 8 NDA. 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. 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.

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. 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 do not believe that 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. Although certain innovative approaches may help increase access to a broader selection of nonprescription drugs for ESRD beneficiaries, we do not consider the transition from prescription to OTC to be innovative for purposes of the TDAPA policy. We believe that making the TDAPA available for Type 8 NDAs may defeat the intent of lowering overall costs for both the ESRD beneficiary and for Medicare, is not needed by the facilities to provide additional support during an uptake period so they can be incorporated into the business model. Over the counter 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, the newness is a reflection of accessibility to the general public without having to obtain a prescription through a licensed practitioner. We believe that these drugs, though new to the market, are not sufficiently innovative to qualify for TDAPA eligibility.

(e) Generic Drugs

We are proposing 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 discussed previously in section II.B.1.b of this proposed rule, 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.

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. An ANDA may not be submitted 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.

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. 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. However, 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.

For example, in June 2018, a report 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]

In June 2018, an article noted that competition has a limited impact on American health care, particularly when it comes to expensive interventions like prescription drugs. Notably, 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. When the first generic finally entered the market, its list price was only slightly less at 539 percent above the original entrant. Economists call this "sticky pricing" and the article notes 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 states that companies have decided it is not in their interest to compete.[13]

For purposes of the ESRD PPS, we believe that we need to strike a balance between enhancing significant renal dialysis drug innovation and encouraging competition through

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

support of innovative drugs that would become optimal choices for ESRD patients and advance their care through improved treatment choices. Our goal in supporting competition among drugs in the ESRD PPS functional categories was to ultimately affect the launch price of new drugs. We now questions whether including all new renal dialysis drugs and biological products as eligible for the TDAPA would help us meet that goal. Rather, we believe 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 goals for the TDAPA policy.

Therefore, we are proposing 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 5 in combination with Type 2, or Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8.

We are soliciting 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 are proposing to exclude should be included, for example, within the NDA Type 3 (new dosage form) the inclusion of intravenous to oral route of administration.

We are also proposing 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 are proposing to change the definition of "ESRD PPS functional category" to replace "biologicals"

with "biological products." We are also proposing to change the definition of "Oral-only drug" to replace "biological" with "biological product."

As compared to the TDAPA policy finalized in the CY 2019 ESRD PPS final rule, we believe 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 coinsurance. Specifically, in the CY 2019 ESRD PPS final rule (83 FR 56932), we finalized that, effective January 1, 2020, the TDAPA would apply for all new renal dialysis drugs and biological products. Since the 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 coinsurance for beneficiaries.

We solicit comment on the proposals to revise the drug designation process regulation at § 413.234 to reflect that certain new renal dialysis drugs would be excluded from eligibility for the TDAPA.

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

Under our proposal, any new renal dialysis drug or biological product that we are not proposing for exclusion in section II.B.1.c.i of this proposed rule, would continue to be eligible for the TDAPA. In the following paragraphs we provide some examples of the types of renal dialysis drugs and biological products that we believe would continue to be eligible for the TDAPA under our proposal, using the descriptions in the NDA classification code referenced in section II.B.1.c of this proposed rule. We note that under our proposal, FDA approvals under

section 351 of the PHS Act, which includes 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

Type 1 NDA refers to drugs containing 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(b) of the FD&C Act or has been previously marketed as a drug in the U.S.

We believe 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. Unlike the drugs proposed to be excluded from the TDAPA as described above, these drugs are generally not line extensions of previously existing drugs. 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

Type 2 NDA is for a drug product that contains a new active ingredient, but not an 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. 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 believe 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. Single enantiomer drugs can lead to fewer drug interactions in the ESRD population, which already has a significant medication burden.[14] We believe 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 believe 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.

(c) Type 4 NDA – New Combination

Type 4 NDA is 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.

We are proposing that new renal dialysis drugs that are classified as a Type 4 NDA

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

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. 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. 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 believe 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 classification code, 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

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.[16] When the Type 9 NDA is submitted, it is given the same NDA classification code as the pending

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

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

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.

Since Type 9 NDA is a new clinical indication, this suggests that a drug company 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 believe renal dialysis drugs that are classified as NDA Types 1, 2, and 4 are all innovative and therefore we propose that these drugs should continue be eligible for the TDAPA as discussed in sections II.B.1.c.ii.(a), II.B.1.c.ii.(b), and II.B.1.c.ii.(c), of this proposed rule. When the "parent NDA" is Type 1, 2, or 4, Type 9 NDA would be a new indication of those innovative drugs. Therefore we believe 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 believe applying the TDAPA with respect to 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

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. 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 classification code 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 believe renal dialysis drugs with the Type 10 NDA classification code 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 company is pioneering a new approach to provide better pharmacologic care for vulnerable ESRD patients with complex medical needs. We believe 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 believe 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 under section 351 of the PHS Act

Under our proposal, 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.

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.

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).

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 of "interchangeability." To meet the additional standard of "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.[17,18,19]

CMS continues to support the development and the utilization of these products that

17 FDA. Guidance for Industry - Questions and Answers on Biosimilar Development and the BPCI Act. December, 2018. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/questions-and-answers-biosimilar-development-and-bpci-act-guidance-industry

18 FDA. Draft guidance for industry - New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2) (when final, this guidance will represent FDA's current thinking on this topic). Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-and-revised-draft-qas-biosimilar-development-and-bpci-act-revision-2

19 FDA. Webinar. Overview of the Regulatory Framework and FDA's Guidance for the Development and Approval of Biosimilar and Interchangeable Products in the US. Available at: https://www.fda.gov/drugs/biosimilars/fda-webinar-overview-regulatory-framework-and-fdas-guidance-development-and-approval-biosimilar-and

contain innovative technology for the treatment of ESRD. 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 proposing 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.

We are aware, however, that there are similar concerns about providing the TDAPA for these products that there are with generics. Specifically, according to a recent report, 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. The researchers noted that the increases were borne solely by Medicare. [20] We will continue to monitor future costs of biosimilar biological products as they pertain to renal dialysis, the TDAPA, and the ESRD PPS.

In summary, with regard to new renal dialysis drugs and biological products that fall

20 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.

within an existing ESRD PPS functional category, we believe that 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 plan 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 note that for new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the purpose of the TDAPA continues to be a pathway toward a potential base rate modification.

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.

d. Proposal to Modify 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 intravenous 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 intravenous 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. 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, we will continue to pay for calcimimetics using the TDAPA in CY 2020.

We stated in the CY 2019 ESRD PPS final rule (83 FR 56943) 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 intravenous product are available, but not for less than 2 years. 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. 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 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). 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. We also believe 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. Finally, this policy is 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). We therefore propose that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, will be 100 percent of ASP. That is, we propose 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."

In addition, under the proposal discussed in section II.B.2.c of this proposed rule, since we currently receive ASP data for calcimimetics, beginning January 1, 2020, we would no longer apply the TDAPA for calcimimetics if we stop receiving the latest full calendar quarter of ASP data for calcimimetics during the TDAPA payment period.

e. Proposed 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 the 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. In this proposed rule, we are proposing a revision to § 413.230 to add paragraph (d) to reflect the TDAPA. We believe this modification is necessary so the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount. This revision to the regulation would not change how the ESRD PPS per treatment payment amount is currently calculated. We are also proposing to revise § 413.230 to include, as part of the calculation of the per treatment payment amount, any Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) as proposed in section II.B.3.b.iii of this proposed rule.

We are also proposing 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, § 414.335(b) describes the training adjustment add-on when erythropoietin (EPO) is furnished to home dialysis patients, whereas § 413.235(c) describes the training adjustment add-on applicable, 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 to apply more generally, rather than just when EPO is furnished and therefore, we are proposing to refer to § 413.235(c). We solicit comment on these proposed changes to § 413.230 to (1) add paragraph (d) to reflect that the TDAPA is a component in the determination of the per treatment payment amount and (2) replace the reference to "§ 414.335(b)" in § 413.230(c) with a more appropriate reference to the training adjustment add-on requirement, which is "§ 413.235(c)."

2. Proposed 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.[21]

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

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

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).

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 noted previously, 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. 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 also note that as discussed in section II.B.1.d of this proposed rule, we are now proposing to modify the basis of payment for the TDAPA for calcimimetics for CY 2020 to ASP+0.

Following publication of the CY 2019 ESRD PPS final rule, we have continued to assess our policy allowing for WAC or invoice pricing if ASP is not available, and we have become 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.

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 note 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 are 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 believe we need 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.

Further, we are 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 anticipate 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,[22] we are 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,[23] 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.[24]

We point 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.[25] MedPAC's recommendations

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22 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

23 Report to Congress, MedPAC, June 2017, page 42. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf,

24 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,

25 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.

in its June 2017 report[26] would require that all Part B drug manufacturers submit ASP data into CMS, whether or not those manufacturers have a Medicaid Drug Rebate Agreement.[27] Based on this data and our own experience with the calcimimetics, we are concerned that manufacturers may not voluntarily report ASP data into CMS. 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 believe 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.

In addition to our concerns about ASP data reporting generally, we are 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 this 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)

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26 Report to Congress, MedPAC, June 2017, pages 10-12. Available at: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf

27 OMB. A Budget for a Better America. Fiscal Year 2020, page 41. Available at: https://www.whitehouse.gov/wp-content/uploads/2019/03/budget-fy2020.pdf

of the Act does not include the discounts that ASP includes.[28] 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 inflated amount beyond what the average cost to ESRD facilities to acquire those drugs. This additional amount would also then increase the coinsurance for the beneficiaries who receive those drugs. We believe 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

We are proposing to revise § 413.234(c) to address the following concerns: (1) increases to Medicare expenditures by the calcimimetics; (2) drug manufacturers not reporting ASP data; 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 note that we are not proposing to modify the current ASP reporting process[29] and our proposals are 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 believe 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 are proposing to allow 3-calendar quarters for drug manufacturers to make ASP available to CMS to enable ESRD facilities to continue to

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28 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,

29 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

receive the TDAPA for a product.

As discussed in section II.B.2.a of the 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 are proposing 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 are therefore proposing 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 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

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. 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 believe we would be overpaying for the TDAPA for those products.

Therefore, we are also proposing to revise the regulatory text at § 413.234(c) to 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 assess pricing for new renal dialysis drugs and biological products eligible for the TDAPA on a quarterly basis. 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).

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 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, not just those in new ESRD PPS functional categories, including composite rate drugs and biological products that fall within an ESRD PPS functional category. A detailed discussion of the TDAPA policy is found in section II.B.1.a of this proposed rule. 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 FDA approved devices. They commented on the lack of FDA approved or authorized new devices 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 medical 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 innovative products and asked CMS to work with the kidney care community to consider if and how new devices or other new 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, 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 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, we are considering whether additional payment may be warranted for certain new and innovative renal dialysis equipment and supplies. In sections II.B.3.a.i and II.B.3.a.ii of this proposed rule is a general description of the IPPS new technology add-on payment (NTAP) and its substantial clinical improvement (SCI) criteria. We believe a process similar to the IPPS process for establishing SCI for the NTAP described in section II.B.3.a.ii of this proposed rule could be used to identify the innovative renal dialysis equipment and supplies for which commenters were requesting additional payment under the ESRD PPS.

We believe 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[30], 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[31], 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

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

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

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 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 § 412.87 specify a 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 medical 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 continued 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 substantial clinical improvement, we work with our medical officers to evaluate whether a technology represents a substantial clinical improvement. 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 Additional Payment for New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

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 have received additional information from dialysis equipment and supply manufacturers and a Technical Expert Panel (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 proposed 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 believe 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 believe 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 note that in order for equipment and supplies awarded through the KidneyX to be eligible for the additional payment under the ESRD PPS proposals in this section of the proposed rule, 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 this proposed rule. We also note that the goals for KidneyX and our proposal in this section 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 in this section are intended to support uptake of new and innovative renal dialysis products 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[32] 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 Additional Payment for New and Innovative Renal Dialysis Equipment and Supplies

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

In consideration of the feedback we have received, we agree that additional payment for certain renal dialysis equipment and supplies may be warranted under specific circumstances outlined in this section of the proposed rule. We are proposing to provide additional payment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities (with the exception of capital-related assets), through a transitional add-on payment adjustment as described further in this proposed rule.

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 are proposing 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 approvals 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 solicit comment on this aspect of our proposal and whether a different FDA marketing approval date—for example, on or after January 1, 2019—might be appropriate.

For new and innovative equipment and supplies, we believe the IPPS SCI criteria and the process used to evaluate SCI can be used as a proxy for identifying new and innovative items worthy of additional payment under the ESRD PPS. 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. CMS is proposing to adopt the IPPS SCI criteria under the ESRD PPS for the same reason. We want to ensure that additional payments 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 believe the same SCI criteria should be used to assess whether a

new renal dialysis equipment or supply warrants additional payment under Medicare.

Therefore, we are proposing 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 additional payment 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 believe that by incorporating the SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have a standard for criteria to meet for both settings. We are also proposing to establish a process modeled after IPPS's process of determining if a new medical technology meets the SCI criteria specified in § 412.87(b)(1) discussed in section II.B.3.a.ii of this proposed rule. That is, we propose that CMS would 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 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.

We note that as described in section II.B.3.a.i of this proposed rule, IPPS has additional criteria that is specific to its payment system, that is, a high cost criteria relative to the MS-DRG payment. We would not 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 adjustment. Since the elements of the IPPS payment system differ from that of the ESRD PPS, we are only

proposing to adopt the SCI criteria in § 412.87(b)(1) at this time.

We are proposing to exclude capital-related assets from the additional payment, 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. This would include certain renal dialysis equipment and supplies. Examples of capital-related assets for ESRD facilities are dialysis machines, water purification systems and systems designed to clean dialysis filters for reuse. We do not believe that we should provide additional payment 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 believe capital-related assets should be excluded from additional payment at this time, and we have proposed an exclusion to the eligibility criteria in new § 413.236(b)(2). However, we note that capital-related 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) as described in section II.B.3.a.ii of this proposed rule, 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.

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 would provide a description of the equipment or supply and pertinent facts related to it that can be evaluated through notice-and-comment rulemaking. 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. We would only consider, for additional payment for a particular calendar year, an application for which the renal dialysis equipment or supply is considered new by February 1 prior to the particular calendar year.

For example, in order to receive additional payment under the ESRD PPS in CY 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 additional payment in the CY 2022 ESRD PPS proposed rule. The evaluation of the eligibility criteria would be in the CY 2022 ESRD PPS final rule. If the renal dialysis equipment or supply qualifies for the additional payment, payment would begin January 1, 2022.

Alternatively, we considered an application deadline of September 1, however, we are proposing an earlier timeframe so that this additional policy would be implemented sooner. However, a September 1 deadline would provide more time initially for manufacturers to submit applications. We solicit comment on the proposed deadline date for the application.

We also solicit comment on the proposed criteria to determine new and innovative renal dialysis equipment and supplies that would be eligible for additional payment. In addition, we are soliciting comment on the use of different evaluative criteria and, where applicable, payment methodologies, for renal dialysis supplies and equipment that may be eligible for an additional payment under the ESRD PPS. These criteria could include cost thresholds for high cost items. We solicit 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 seek comment on whether to use FDA's pre-market approval and De Novo pathways as a proxy for or in place of the proposed SCI criteria. In addition, we are soliciting comment on potential implementation challenges, such as what sources of data that CMS should utilize to assess SCI. We are also soliciting comment on the proposed process that would be used to determine SCI. Also, we are soliciting comment on the benefits and drawbacks of the SCI criteria proposed in this rulemaking.

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

With respect to the new and innovative renal dialysis equipment and supplies discussed in section II.B.3.b.i of this proposed rule, we are 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 note that, unlike for 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 their high cost criteria payment calculation, the ESRD PPS has a single per treatment payment amount. Therefore, we must propose 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 are proposing that ESRD facilities would report the HCPCS code, when available, and their corresponding charge for the item. 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 are not proposing 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. We are proposing to obtain a pricing indicator that

requires the item to be priced by Medicare Administrative Contractors (MACs). We propose to adopt a process that utilizes invoiced-based pricing. We note that there are instances that 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, in the CY 2019 Physician Fee Schedule final rule (83 FR 59663), we discuss 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 believe using invoices for new drugs and drugs without national pricing is a similar situation to dealing with new and innovative renal dialysis equipment and supplies that do not have a national price.

We believe 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 believe 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).[33] 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 coinsurance obligations for beneficiaries. For this reason, we believe 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 develop a payment rate. 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.

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.

Once there is sufficient payment data across MACs, we would consider establishing a national price for the item through notice and comment rulemaking. We are inviting 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 proposed rule. We also solicit comment on other pricing criteria and other verifiable

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

sources of information that should be considered.

As discussed in section II.B.3.a.i of this proposed rule, under the IPPS's NTAP payment policy, the additional payment for cases with high costs involving eligible new technologies preserves some of the incentives under the average-based payment system. The payment mechanism is based on the cost to hospitals for the new technology. Under § 412.88, Medicare pays a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. If the costs of the discharge exceed the full MS-DRG payment, the additional payment amount equals the lesser of the following: 50 percent of the costs of the new medical service or technology; 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.

To mitigate the Medicare expenditures incurred as a result of the transitional add-on payment adjustment proposal discussed later in this section of the proposed rule, we are proposing to base the additional payment on 65 percent of the MAC-determined price. We noted 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. We believe 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 are proposing to base the transitional add-on payment adjustment for new and innovative equipment and supplies on 65 percent of the MAC-determined price. We are also soliciting 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 transitional add-on payment adjustment 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

We are proposing to provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities that meet the eligibility criteria described in section II.B.3.b.i of this proposed rule. That is, the payment adjustment would only be available for renal dialysis equipment and supplies that meet the proposed eligibility criteria discussed in section II.B.3.b.i of this proposed rule. We would refer to the adjustment as the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

We would establish the TPNIES based on our authority under section 1881(b)(14)(D)(iv) of the Act, which provides in relevant part that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. We believe this authority is broad enough to support the creation of the TPNIES.

We acknowledge that ESRD facilities have unique challenges with regard to implementing new renal dialysis drugs and biological products as discussed in section II.B.1.a of this proposed rule, and we believe 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 believe 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 are proposing 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 would monitor renal dialysis service utilization trends, after which we are proposing that the item would become an eligible outlier service as provided in § 413.237. Therefore, we are proposing revisions to § 413.237(a)(1) to reflect outlier eligibility once the TPNIES period ends. We believe 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 believe 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.

We further believe 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, this transitional add-on payment adjustment 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 propose 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 note that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary coinsurance, 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 inpatient hospital payment policies, we believe that the proposed TPNIES would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment and supplies.

The intent of the TPNIES for new and innovative equipment and supplies 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. 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 whenever something new is made available.

Therefore, we propose to add § 413.236, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies. We propose to add § 413.236(a) to state that the basis for the TPNIES 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 also propose to add § 413.236(b) to require 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, (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 in that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries, 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 propose to add § 413.236(c) to establish a process for SCI determination and deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. That is, we propose 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 propose that

we would only consider a complete application received by CMS by February 1 prior to the particular calendar year.

We also propose to add § 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 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 propose 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 are also proposing to add paragraph (e) to § 413.230 to reflect the TPNIES. We believe this modification is necessary so the regulation appropriately reflects all inputs in the calculation of the per treatment payment amount.

Since we are adding paragraphs (d) (discussed in section II.B.1.e of this proposed rule) and (e) to § 413.230, we also propose a technical change to remove "and" from the end of

§ 413.230(b). We propose that the "and" would be added to the end of § 413.230(d).

In addition, we are proposing 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 propose 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 are proposing 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 are also proposing 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.

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 affects patient access to new and innovative products. We are soliciting 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." Medicare has no specific rules, regulations or instructions with regard to HUDs. We are 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.

4. Proposal to Discontinue 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).

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 also 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 we believed 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). 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 believe 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. Proposal to Discontinue the Application of the EMP to Outlier Payments under the ESRD PPS

Effective January 1, 2020, CMS is proposing to no longer apply the EMP under the ESRD PPS. 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. 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 would continue to require ESRD facilities to report all necessary information for the ESRD Quality Incentive Program. 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.[34] 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, 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 believe that 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 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 believe 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.

We request public comments on our proposal to discontinue the application of the EMP under the ESRD PPS.

5. Proposed CY 2020 ESRD PPS Update

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

a. Proposed 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 propose 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 propose to estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI), forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. 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 is 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) is projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2020 ESRD market basket adjusted for MFP is 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.

As is our general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket update or MFP adjustment), we propose to use such data to determine the final CY 2020 market basket update and/or MFP adjustment.

For the CY 2020 ESRD payment update, we propose 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).

b. The Proposed CY 2020 ESRD PPS Wage Indices

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 would update the wage indices to account for updated wage levels

in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The proposed CY 2020 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed 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 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). Beginning in CY 2020, we are proposing that the statewide urban average based on the average of all urban areas within the state also 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.

We were recently made aware of a minor calculation error in the file used to compute the ESRD PPS wage index values for this proposed rule. We are posting the corrected wage index values on the ESRD PPS payment page and we will correct this error when computing the ESRD PPS wage index values and payment rates for the final rule.

c. Proposed 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 propose 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 propose 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 recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS.

In the CY 2019 ESRD PPS final rule (83 FR 56968), we stated that based on the CY 2017 claims data, outlier payments represented approximately 0.80 percent of total payments. For this proposed rule, as discussed in section II.B.5.c.ii of this proposed rule, CY 2018 claims data show outlier payments represented approximately 0.5 percent of total payments.

i. CY 2020 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2020, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2018 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2018 claims data. We note that, beginning in CY 2020, the total expenditure amount includes payments made for calcimimetics under the TDAPA policy (calculated to be $21.15 per treatment). The impact of this 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 proposed estimates for this rule. The estimates for the proposed 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 Proposed outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)**	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**

	Column I Final outlier policy for CY 2019 (based on 2017 data, price inflated to 2019)*		Column II Proposed 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	$32.27	$38.15
Adjustments				
Standardization for outlier services	1.0503	0.9779	1.0692	0.9789
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$35.18	$38.51	$33.82	$36.60
FDL amount that is added to the predicted MAP to determine the outlier threshold	$57.14	$65.11	$44.91	$52.50
Patient-months qualifying for outlier payment	7.2%	8.2%	10.8%	9.9%

*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; $52.50) 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 $36.60. For pediatric patients, there is a decrease in the FDL amount from $57.14 to $44.91. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $35.18 to $33.82.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2020 would be 9.9 percent for adult patients and 8.2 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. 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 proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments, as well as co-insurance obligations for beneficiaries with renal dialysis services eligible for outlier payments.

d. Proposed 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, any applicable outlier payment and training adjustment add-on, the TDAPA (as proposed in section II.B.1.e of this proposed rule), and the TPNIES (as proposed in section II.B.3.b.iii of this proposed rule).

ii. Annual Payment Rate Update for CY 2020

We are proposing an ESRD PPS base rate for CY 2020 of $240.27. This update reflects several factors, described in more detail as follows:

- Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2020 projection for the proposed ESRDB market basket is 2.1 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 proposed MFP adjustment for CY 2020 is 0.4 percent, thus yielding a proposed update to the base rate of 1.7 percent for CY 2020. Therefore, the proposed 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 are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 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 becomes 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 CY 2020 proposed wage index budget-neutrality adjustment factor is 1.004180. This application would yield a CY 2020 ESRD PPS proposed base rate of $240.27 ($239.27 × 1.004180 = $240.27).

In summary, we are proposing a CY 2020 ESRD PPS base rate of $240.27. This amount reflects a proposed market basket increase of 1.7 percent and the proposed CY 2020 wage index budget-neutrality adjustment factor of 1.004180.

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 a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies

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

B. Proposed 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 this proposed rule, the CY 2020 proposed ESRD PPS base rate is $240.27, which reflects a proposed market basket increase of 2.1 percent reduced by the multifactor productivity adjustment of 0.4 percentage points, that is, 1.7 percent, and application of the proposed CY 2020 wage index budget-neutrality adjustment factor of 1.004180. Accordingly, we are proposing 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 this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated above, we are proposing a CY 2020 AKI dialysis payment rate of $240.27, adjusted by the ESRD facility's wage index.

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

A. Background and Proposed Regulation Text Update

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 83 FR 56922. We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 178.

As we discuss in section IV.C.2 of this proposed rule, we are proposing to adopt the baseline period and performance period for each payment year automatically by advancing each

period by 1 year from the baseline and performance period that were adopted for the previous payment year.

We propose to revise the requirements at § 413.178 by redesignating paragraphs (d) through (f) as paragraphs (e) through (g), respectively. In addition, we propose to add a new paragraph (d) to specify the data submission requirements for calculating measure scores. Specifically, we are proposing to codify the requirement that facilities must submit measure data to CMS on all measures. This proposed regulation text codifies previously finalized policies and will make it easier for the public to locate and understand the Program's quality data submission requirements.

Additionally, the proposed text in new paragraph (d)(2) would codify our proposed policy 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 are proposing 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. This new option will provide facilities with flexibility under the ECE process. We are proposing this provision to provide clear guidance to the public on the scope of our ECE process.

We invite public comments on these proposals.

B. Proposed Update to Requirements Beginning with the PY 2022 ESRD QIP

1. PY 2022 ESRD QIP Measure Set

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 clinical measure 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.
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

2. Estimated 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 this proposed rule, we are estimating in Table 4 the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2022 clinical measures using data from 2016 and 2017. We intend to update these standards, using CY 2018 data, in the CY 2019 ESRD PPS final rule. We also note that we are proposing in this proposed rule to convert the STrR measure from a clinical measure to a reporting measure and that if that proposal is finalized, we would not update these standards for the STrR measure.

TABLE 4: Estimated 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	52.61%	63.69%	76.11%
Catheter Rate	18.24%	11.15%	5.02%
Kt/V Comprehensive	92.98%	96.88% (96.83%)*	99.14% (99.10%)*

	(92.75%)*		
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.

3. Proposed Changes to the Scoring Methodology Previously Finalized for the PY 2022 ESRD QIP

a. Proposed Update to the Scoring Methodology for the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

There are currently 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. 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. 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. The current scoring methodology for the NHSN Dialysis Event reporting measure was finalized in the CY 2017 ESRD PPS final rule, 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 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 5 for the current scoring distribution.

TABLE 5: Current 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

As we have accumulated experience with this policy, we are concerned that new facilities and facilities for which CMS grants an ECE for part of the performance period that applies for a payment year are not eligible to receive a score on the NHSN Dialysis Event reporting measure because they are not eligible to report data for the full 12-month period. As a result, we do not believe that this policy appropriately accounts for the effort made by these facilities to report these data for the months in which they are 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. In addition, if a facility is aware that it will not be eligible to receive a score on the NHSN Dialysis Event reporting measure, we are concerned that the facility will not be incentivized to report data at all for that payment year.

We have therefore reconsidered our previous policy. We propose 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 propose 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 propose to assign scores for reporting different quantities of data as summarized in Table 6.

TABLE 6: 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 believe that it is 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 have as comprehensive as possible a view of these facilities' performance on this important clinical topic. We continue to believe that complete and accurate reporting of NHSN data is critical to maintaining the integrity of the NHSN surveillance system, enables facilities to implement their own quality improvement initiatives, and enables the Centers for Disease Control and Prevention (CDC) to design and disseminate prevention strategies. We believe the fairest way to balance these goals is 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 are not proposing changes to the NHSN BSI clinical measure's scoring methodology and will continue to require that facilities report data for the full 12 months of data in order to receive a score on that measure.

We seek comment on these proposals.

b. Proposal to Convert 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 (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).

We are currently in the process of examining the concern raised by commenters about the validity of the modified STrR measure, and we 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 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 are in the process of evaluating the concern raised by commenters to the CY 2019 ESRD PPS proposed rule , and we intend present our analyses and measure changes to the NQF under an ad hoc review of the STrR clinical measure later this year before making a final decision regarding implementation in the ESRD QIP. Additionally, any substantive changes to the STrR that result from this process may require

a MAP review prior to any future implementation effort. Under the first policy alternative, the Program would continue use of a measure endorsed by NQF, and if a facility does 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 scores at the median used in the mTPS calculation for all measures, it will receive the same TPS as the mTPS and therefore not receive a payment reduction. However, we rejected the first policy alternative because it would score facilities based on their performance on a measure whose validity we are currently examining.

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 current concerns regarding measure validity may call into question the capacity for current data to adequately capture transfusion rates attributable to facilities, we believe 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 are continuing to examine this issue. We would like 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 believe 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 are also proposing that, beginning with PY 2022, we would score the STrR reporting measure as follows: facilities that meet previously finalized minimum data and eligibility requirements will receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. We are proposing 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. A patient-year at risk is 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 believe 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.

We seek comments on these proposals.

c. Proposed Update to the MedRec Reporting Measure's 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 inadvertently used the term "patient-months" in the MedRec reporting measure's scoring equation. 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.. 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.

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 measure), the Serum Phosphorus reporting measure (finalized for removal beginning with the PY 2021 ESRD QIP measure), and the Ultrafiltration reporting measure.

We are therefore proposing to revise the scoring equation for the MedRec reporting measure so that the scoring methodology accurately describes our intended policy. We propose to score the MedRec reporting measure using the following equation, beginning with the PY 2022 ESRD QIP.

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \text{ X } 12 \right) - 2$$

We seek public comment on this proposal.

Additionally, in section IV.B.4 of the CY 2019 ESRD PPS final rule, we 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 are clarifying 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.

4. Proposed 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 this proposed rule, we are proposing 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 are eligible to report the measure, beginning with the PY 2022 ESRD QIP. To accommodate this proposed policy, we are proposing 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. Table 7 summarizes 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 7: 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 (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 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

5. Estimated Payment Reduction for the PY 2022 ESRD QIP

Under our current policy, a facility will not receive a payment reduction in connection with its performance 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.[35]

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 estimate using available data that a facility must meet or exceed a minimum TPS of 53 in order to avoid a payment reduction. We note that the mTPS estimated in

[35] 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 recently codified definition of the minimum TPS.

this proposed rule is based on data from CY 2017 instead of the PY 2022 baseline period (CY 2018) because CY 2018 data are not yet available. We will update and finalize the mTPS using CY 2018 data in the CY 2020 ESRD PPS final rule.

We refer the reader to Table 4 for the estimated values of the 50th percentile of national performance for each clinical measure. 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 8.

TABLE 8: Payment Reduction Scale for PY 2022 Based on the Most Recently Available Data

Total performance score	**Reduction (%)**
100-53	0%
52-43	0.5%
42-33	1.0%
32-23	1.5%
22-0	2.0%

We intend 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.

6. Data Validation Proposals for PY 2022 and Beyond

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: the CROWNWeb 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). 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 refer readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

We are proposing 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. 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 are proposing 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 are proposing to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and are proposing to continue for PY 2023 and subsequent years. We continue to believe that the purpose of our validation programs is to ensure the accuracy and completeness of data that are scored under the ESRD QIP, and we believe 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 signal our commitment to accurate reporting of the important clinical topics covered by the NHSN measures that we have adopted.

We welcome public comments on these proposals.

C. Proposals for the PY 2023 ESRD QIP

1. Continuing Measures for the PY 2023 ESRD QIP

Under our previously-adopted policy, we are continuing all measures from the PY 2022 ESRD QIP for PY 2023. We are not proposing 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

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. We therefore propose to establish CY 2021 as the performance period for the PY 2023 ESRD QIP for all measures. Additionally, we propose 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 the 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 propose 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 welcome comment on these proposals.

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. 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.

a. Performance Standards for Clinical Measures in the PY 2023 ESRD QIP

At this time, we do 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 do not have CY 2019 data. We intend 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). We will continue use of these 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).[36]

We are not proposing to change our 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),[37] 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). We will continue use of the Ultrafiltration Rate reporting measure's scoring policy in PY 2023. In section IV.B.3.c of this proposed rule, we propose to use facility-months instead of patient-months when scoring the MedRec reporting measure and clarify 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 performance period. Those proposals, if finalized, would apply to PY 2023 and subsequent payment years.

5. Proposals for Weighting the Measure Domains, and for Weighting the TPS for PY 2023

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of TPS, the Care Coordination Measure Domain a weight of 30 percent of TPS, the Clinical Care Measure Domain a weight of 40 percent of TPS, and the Safety Measure domain a weight of 15 percent of TPS, for the PY 2022 ESRD QIP (83 FR 57011 through

[36] Please note that we are proposing to redesignate paragraph (d) as subparagraph (e) in this proposed rule.
[37] As noted above, we are proposing to redesignate paragraph (d) as subparagraph (e) in this proposed rule.

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). We are proposing to continue use of the PY 2022 measure weights for the PY 2023 ESRD QIP and subsequent payment years. We also proposing to continue use of the PY 2022 measure weight redistribution policy in the PY 2023 ESRD QIP and subsequent payment years.

We welcome comments on these proposals.

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).

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 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. In accordance with 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 or items paid under Healthcare Common Procedure Coding System (HCPCS) codes for miscellaneous items. 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 catalogue 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, in revising the DME MAC statement of work, CMS clarified to the DME MACs that manufacturer's suggested retail prices (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 many cases, a single manufacturer may produce a new item, and pricing information may therefore be limited to the MSRP. In these situations, unlike other items and services paid for under Medicare, there is not yet independently substantiated pricing information. In addition, similar items are not 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 to the DME MACs to update the DMEPOS fee schedule, we include a list of new HCPCS codes, which are then 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 procedures that permit public consultation for coding and payment determinations for new DMEPOS items under Medicare Part B 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's preliminary decision has been developed, the 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 applicable update (annual or quarterly) to our contractors and via our website. 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 number of approved new DMEPOS codes is not finalized until shortly before the release of the HCPCS dataset, 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, contractors are instructed to make every effort to determine whether the item has a pricing history and profile. If there is a pricing history, that is, the items and services described by the new code were paid for in the past under other codes based on the fee schedule amounts for the other codes, the fee schedule amounts used to pay for the item previously 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 is 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 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). 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, CMS 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 address 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 technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments

for new technology items and services. 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. The commenters expressed concern that the current gap-

filling methodology assumes that all products within a given HCPCS code have equal characteristics, minimum specifications, and the gap-filling method does not account for relative quality, durability, clinical preference, and overall market demand. Thus, the commenters were concerned that the calculation of a gap-filled amount for a new item does not reflect the utilization of an existing item.

B. Current Issues

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 what CMS considers when determining whether new items are comparable to other DMEPOS items. Some have asked for a process that is more predictable in determining what 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

We have heard frequently from manufacturers that do not agree that their newly

developed DMEPOS item is comparable to older technology DMEPOS items and services. 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.

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 9, 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 9 under the five main components are examples of various attributes CMS evaluates within each category. We believe that establishing a set framework and basis for identifying comparable items in regulation would improve the transparency and predictability of establishing fees for new DMEPOS items.

TABLE 9: 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

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, 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 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 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 a1986/87 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 addition to using information from supplier or commercial price lists, CMS can determine the relative supplier costs of furnishing new DMEPOS items compared to other DMEPOS items with existing fee schedule amounts by using technology assessments to determine the relative cost of a new DMEPOS item versus older items for which Medicare fee schedule amounts have been established. Under this option for obtaining pricing information, the cost of new DMEPOS items relative to the cost of items with existing fee schedule amounts would be assessed and used to establish fee schedule amounts for the new DMEPOS items. The assessment would be made by biomedical engineers, certified orthotists/prosthetists and other experts at CMS and its contractors. Payment amounts for new items and services under the old reasonable charge payment methodology were sometimes gap-filled using relative value scales, which filled gaps in charge data for an item based on the relative value or cost of the item compared to other items with charge data. This same concept can be used to price new

DMEPOS items relative to existing DMEPOS items under the fee schedule. In the past, we have contracted with companies to conduct technology assessments, and the process involved analyzing samples of the product(s) being priced as well as older technology items. Under this option, it may be necessary for us to obtain samples of new items as well as existing items if the relative cost of the items cannot be determined without obtaining samples. For more complex items, it may be necessary to use a separate technology assessment contractor in addition to skilled CMS and contractor personnel such as biomedical engineers to conduct the technology assessment. To clarify, this option is not the same as using fees for comparable items, where existing fee schedule amounts for older items are used for newer items determined to be comparable to the older items. If new items are not comparable to older items with existing fee schedule amounts, the supplier cost of furnishing the new item(s) can be compared to the supplier cost of furnishing an older item(s) with established fee schedule amounts and the relative difference in the cost of the new item versus the older item(s) can be determined using a technology assessment.

Once the relative cost of the new item is determined, a pricing percentage would be established based on the results of the technology assessment to establish the fee schedule amount for the new DMEPOS item. For example, if it is determined that the cost of a new DMEPOS item is approximately twice the cost of existing DMEPOS item(s), the pricing percentage would equal 200. Thus, if the fee schedule amount for an existing DMEPOS item is $500, then the fee schedule amount for the new DMEPOS item would be $1,000 (200 percent of $500 or $500 multiplied by two). Another example is when it is determined that the cost of the new DMEPOS item is approximately 75 percent of the cost of the old DMEPOS item(s). For example, if the fee schedule amount for the old DMEPOS item is $500, then the fee schedule

amount for the new DMEPOS item would be $375 (75 percent of $500 or $500 multiplied by 0.75). We believe using the relative cost of new items versus older items keeps all DMEPOS items (old and new) on a level playing field and priced in accordance with the historic reasonable charges for DMEPOS in general. We believe this method also helps foster innovation since new items that cost more would be priced based on these higher costs relative to older items with lower costs. We propose 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. For example, if a code is added for a new type of manual hospital bed and supplier or commercial prices are 20 times higher than the fee schedule amounts for all other types of manual hospital beds, we would use a technology assessment of the supplier costs of furnishing different types of manual hospital beds to determine the relative supplier costs of furnishing the new type of manual hospital bed, which in turn would be used to establish the fee schedule amounts for the new type of manual hospital bed. The technology assessment is a tool for obtaining more information about the costs of the new item relative to the older items.

To summarize, we propose to add a provision to the regulations at §414.236 that addresses the continuity of pricing when items are re-designated from one HCPCS code to another. For new items without a pricing history, we propose to add a provision to the regulations at §§414.112 and 414.238 to establish five 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 are proposing to use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. We also propose that if it is determined that there are no comparable items to use for gap-filling purposes, 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 propose 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.

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. We anticipate the need to continue the establishment of interim fees and in certain cases, an interim fee could be effective as long as 6 months to a year if complex technology assessments are needed in order to establish a fee schedule amount for the new item. Changes to the national DMEPOS fee schedule files can be made on a quarterly basis, and this can include corrections of errors made in calculating fee schedule amounts (see section 60.2 of

chapter 23 of the Medicare Claims Processing Manual). Corrections to errors in fee schedule amounts are made on a quarterly basis due to limited resources and the need to test changes to the fee schedule files and claims processing edits and systems.

As explained in section V.B.4 of this proposed rule, the time during which temporary, local fee schedule amounts may be necessary for payment purposes could be affected by the process used to obtain public consultation and feedback from stakeholders on the pricing of new items.

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. This is also why we believe we should use technology assessments to price newer items if the newer items are not comparable to older items and available supplier invoices and/or commercial pricing information is either not verifiable or appears to be unreasonable.

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 are proposing 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 are not proposing similar one-time increases in fee schedule amounts established using supplier or commercial prices, however, we invite 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. Provisions of the Proposed Rule

1. Continuity of Pricing When HCPCS Codes are Divided or Combined

We propose 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 propose 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 associated with, 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, use 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.

2. Establishing Fee Schedule Amounts for New HCPCS Codes for Items and Services Without a Fee Schedule Pricing History

We are proposing 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 propose 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 propose 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 propose 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 propose 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, 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 propose 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 propose 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 propose that the annual deflation factors would be specified in program instructions and would be 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

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 propose 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 are not proposing a similar adjustment if supplier or commercial prices increase by less than 15 percent, but we invite comments on this issue.

We propose 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. We propose that these technology assessments would be performed by biomedical engineers, certified orthotists and prosthetists, and CMS, and others knowledgeable about DMEPOS items and services, to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts. We propose 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). For example, if it is determined that the cost of the item and services described by the new code(s) is approximately twice the cost of the items and services described by the code(s) with existing fee schedule amounts, the pricing percentage would be 200, and the current fee schedule amount for the old code(s) would be multiplied by two to establish the fee schedule amounts for the new code(s). Or, if it is determined that the cost of the items and services described by the new code(s) is approximately 75 percent of the cost of the items and services described by the code(s) with existing fee schedule amounts, the pricing percentage would be 75. The pricing percentages would be applied to the current fee schedule amounts for HCPCS codes with existing fee schedule amounts to calculate the fee schedule amounts for new HCPCS codes without a fee schedule pricing history.

We propose 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 and had established fee schedule amounts using data from the fee schedule base period 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. Technology assessments are a tool for obtaining more information about the relative costs of the new item to the older items.

We are soliciting comments on these proposals.

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.[38]

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 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, which has led to the enactment of legislation (as outlined in the background section of this proposed regulation) to safeguard beneficiaries and the Medicare Trust Funds. 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.

[38]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 January 8, 2019.

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 propose 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 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 proposed 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.

Our regulations at § 410.38(g)(4) require 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). Section 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. CMS selects items from the Master List to require prior authorization as a condition of payment and publishes notice of such items in the **Federal Register**. Items on the Master List are updated annually, based on payment thresholds and changes in vulnerability reports, as well as other factors described in § 414.234.

We note 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.

The purpose of this subsequent proposal is to streamline the existing requirements and reduce provider or supplier confusion, while maintaining the concepts of practitioner involvement, order requirements, and a prior authorization process. We believe streamlining our requirements would further 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. Provisions of the Proposed Regulations

1. Technical Corrections to § 410.38(a) and (b).

We propose 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 propose 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 are therefore proposing 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.

2. Definitions

We are proposing to update § 410.38(c) to include definitions related to certain requirements for the DMEPOS benefit.

We are proposing to add new definitions, redesignate existing definitions within the regulatory text, and amend existing definitions. We believe 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 propose at § 410.38(c) to include the following terms:

- Physician means a practitioner defined in section 1861(r)(1) of the Act. We are proposing this definition as paragraph (c)(1) and we note that it is 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 are proposing this definition as paragraph (c)(2).

- 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 have a similar definition in our current regulation but § 410.38 required revisions to accommodate the proposed unified conditions of payment. We are proposing this definition as paragraph (c)(3).
- 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. 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, the written order/prescription must additionally be communicated to the supplier before the delivery of the item. As discussed further in this proposed rule, we would standardize the elements of written orders/prescriptions provided for DMEPOS. We are proposing this definition as paragraph (c)(4).
- Face-to-face encounter means an in-person or telehealth encounter between the treating practitioner and the beneficiary. The face-to-face encounter is 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. As discussed further in this proposed rule, we would standardize the face-to-face and documentation requirements for certain DMEPOS. We are proposing this definition as paragraph (c)(5).

- Power Mobility Device (PMD) means 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. Our proposal is the same as our current regulatory definition of this term. Section 410.38(c)(1) required reformatting to accommodate the proposed unified conditions of payment and therefore, we are proposing this definition as paragraph (c)(6).
- 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 are specified in proposed § 414.234(b). 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 are proposing this definition as paragraph (c)(7).
- 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, 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 are proposing this definition as paragraph (c)(8). We note that Required Face-to-Face Encounter and Written Order Prior to Delivery List is distinct from the "Required Prior Authorization List," as defined in existing § 414.234(c)(1)(i).

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 currently 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. We propose 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 specify the criteria for this list in § 414.234.

Our proposal 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. In determining DMEPOS appropriate for inclusion in the Master List, we believe there to be 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 believe it is appropriate for the Master List to 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. As such, we propose to have a single Master List of items potentially subject to face-to-face and written order prior to delivery and/or prior authorization requirements. (See Table 10: Proposed 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 note 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 are proposing 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 legislative 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 we established in accordance with section 1834(a)(11)(B) of the Act. 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 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 do not require it under our current conditions of payment. The remainder of items on the proposed Master List are both currently subject to a face-to-face encounter and a written order prior to delivery requirements as a condition of payment, and potentially would be subject to these conditions of payment under our proposal. All 135 items on the current list potentially subject to prior authorization are also included in our proposed Master List. This proposal would outline the inclusion criteria that developed the proposed Master List of 413 items potentially subject to these conditions of payment.

While the Master List created by this proposed rule 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 propose 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.

The following hypothetical data patterns are not factual, but rather provided for exemplary purposes, 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 also note 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. Under our proposal, motorized and power wheelchairs would also potentially be subject to the prior authorization requirement. We think 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 believe 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 note that programmatic changes, including competitive bidding, had the overall impact of lowering the payment amount for certain items, which is the reason we are proposing to lower these cost thresholds. We are proposing 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 are proposing 1.5 percent to capture the items with the highest allowed amounts, while not creating an overly inclusive list. However, we recognize that item(s) may fail to meet the $500 purchase, $50 rental, or cumulative cost thresholds identified in this proposed rule; nonetheless, such items may demonstrate aberrant billing patterns inconsistent with predictable claim volumes.

We 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. We previously captured reports dating as far

back as 2007; however, we have learned that billing practices may be subject to 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 this proposed rule, we propose to redefine 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 add a new Master List inclusion criteria to capture current aberrant billing patterns. We believe the Master List, as it appears in this proposed rule, is a good representation of those items that may pose risk to the Medicare Trust Funds. If this proposed rule is finalized as proposed, 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 propose 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.

b. Notice and Maintenance of the Master List

We propose at § 414.234(b)(2) that the Master List would be self-updating, at a minimum, annually. The current "self-updating" process remains unchanged and includes applying the criteria to items that appear on the DMEPOS fee-for-service payment schedule. That is, items on the DMEPOS Fee Schedule that meet the payment threshold (for monthly rentals, purchases, or cumulative impacts) are 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 would be added based on findings of aberrant billing patterns (meeting the above inclusion criteria in section VI.B.3.a of this proposed rule) that are not otherwise explained. We believe the proposed

inclusion criteria are capable of capturing more current vulnerabilities. However, we also believe that the current standard process in which items on the list expire after 10 years if they have not otherwise been removed is appropriate 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. To that end, we propose to keep this timeframe, and further clarify 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.

All other list maintenance processes currently specified in § 414.234(b) would be maintained with two exceptions: (1) first, we propose to allow the Master List to be updated as needed and more frequently than annually (for example, to address emerging billing trends). (2) Second, we are also making technical changes to the language in § 414.234(b) to reflect the proposed new cost thresholds and report years discussed in this proposed rule. We would maintain our current process 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.

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. Analysis of a 1-year snapshot of claims indicates that approximately 97 percent of beneficiaries receiving DMEPOS have 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 existing DME List of Specified Covered Items, which requires a face-to-face encounter and a written order prior to delivery. While we believe this information helps provide important context, we note that this 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 propose 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." In this way, we have 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 Required Face-to-Face Encounter and Written Order Prior to Delivery List, based on those items identified to be of highest risk. Tailoring the lists in this way significantly reduces any potential provider impact—and could even decrease the scope of impacted items and providers.

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. 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 propose 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 may 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 this list is not exhaustive. We note that we have not proposed an all-inclusive list of factors to account for the fluidity of program operations and associated vulnerabilities, and believe this is critical to protect beneficiaries, the program, and industry. We solicit 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 also note that this notice and comment rulemaking provides the forum for stakeholders to comment on the proposed Master List from which items may be selected in the future to be subject to the Face-to-Face Encounter and Written Order Prior to Delivery requirement.

As previously stated, we propose 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 propose at § 410.38(d)(2) that any telehealth encounter must meet the existing telehealth requirements of § 410.78 and § 414.65. Telehealth services currently are permitted to be used to satisfy the DME face-to-face encounter requirements. Proposed § 410.38(d)(2) emphasizes 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, 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 propose at § 410.38(d)(3) to clarify the documentation necessary to support the face-to-face encounter and associated claims for payment. This documentation 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 our proposed definition in § 410.38(c)(5) of a face-to-face encounter and required documentation in § 410.38(d)(3) are 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 notes corroborate, together they can be used to support medical necessity of an ordered DMEPOS item.

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 propose 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. Since the industry has become accustomed to the 6-month timeframe, we believe this timeframe is relevant, and changing it would create unnecessary confusion. Therefore, if finalized as proposed, a face-to-face encounter would be consistently required within 6 months of a written order prior to delivery for those items for which a face-to-face encounter is required.

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.

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. We do not believe this proposed rule would create any new burdens for the medical review process, but we ask commenters for feedback on this assumption.

b. Notice and Application of the Required Face-to-Face Encounter and Written Order Prior to Delivery List

We propose 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. This is consistent with our current practices for items selected from the Master list of items frequently subject to unnecessary utilization. Any DMEPOS item included on this 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 propose 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. If 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.

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 propose 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. Similar to the requirements at current § 414.234(c)(1)(ii), we propose that we may decide to select and implement prior authorization of an item(s) nationally or, in collaboration with the DME MACs locally. We propose 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. However, CMS may later elect to exempt suppliers demonstrating compliance from such requirements through the prior authorization process. We believe this proposal meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and provider/supplier burden.

We specify at § 414.234 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 duplicates of the same items 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 solicit 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 also note that this notice and

comment rulemaking provides the forum for stakeholders to comment on the proposed Master List from which items may be selected in the future to be placed on the Required Prior Authorization List.

We note 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 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. 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. 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. If this proposed rule is finalized as proposed, 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 Required Prior Authorization List. Accordingly, there may be a delay in the adoption of this proposed operational change from the date of publication.

As previously stated in the November 2015 final rule, CMS established a prior authorization process for certain DMEPOS items. In 2017, CMS operationalized a prior authorization program, based on the regulatory process codified in 2015, which was initially established in four states for certain PMDs and subsequently expanded nationally (81 FR 93636). The DMEPOS items currently subject to the prior authorization requirement also meet the

proposed Master List inclusion criteria, in this rule, and would continue to be eligible for prior authorization if the proposed criteria are finalized as proposed. To date, feedback related to the DMEPOS prior authorization process has been largely positive; however, the majority of comments have been from suppliers. We encourage all stakeholders, including those representing beneficiaries and Medicare consumer advocacy organizations, to submit their comments about prior authorization during the public comment period, as specified in the "ADDRESSES" section of this proposed rule.

We propose that the items currently subject to prior authorization would be grandfathered into the prior authorization program, if this rule is finalized as proposed, until the implementation of the first Required Prior Authorization List (which would be published subsequent to the 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, if finalized as proposed. We would maintain the current process, as described in § 414.234, of publishing in the **Federal Register** and on the CMS website the Required Prior Authorization List at least 60 days prior to the effective date.

We propose to retain the documentation requirements for submitting prior authorization requests at § 414.234(d); however, we are proposing to add a reference to encompass the payment requirements proposed at § 410.38. In addition, we propose to retain the process for submitting prior authorization requests and receiving responses, but propose restructuring § 414.234(e) to conform to the formatting of the preceding paragraphs.

We propose 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, as described in current § 414.234(f). 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.

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** with 60-day notice before implementation. We are not proposing any changes to this section. In addition, all other prior authorization processes described in § 414.234 not mentioned in this proposed 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 would maintain our current process, as outlined in § 414.234, and publish a 60-day **Federal Register** notice and post on the CMS website when items are placed on the Required Prior Authorization List.

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 propose at § 410.38(d)(1) to adopt one set of required written order/prescription elements for orders/prescriptions 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 propose 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 propose 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 propose at § 410.38(d)(1) that if the rule is finalized as

proposed, DME MACs 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 this proposed rule. In addition, we believe item-specific coverage requirements may be included in national or local coverage documents, as appropriate. Therefore, we propose to delete the coverage requirements currently 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.

TABLE 10: PROPOSED 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

HCPCS	Long Description
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
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

HCPCS	Long Description
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)
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))

HCPCS	Long Description
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
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

HCPCS	Long Description
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
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

HCPCS	Long Description
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
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

HCPCS	Long Description
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 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

HCPCS	Long Description
	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 Capactiy 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
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

HCPCS	Long Description
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
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

HCPCS	Long Description
	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 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

HCPCS	Long Description
	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-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

HCPCS	Long Description
	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
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

HCPCS	Long Description
	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-Fabricated
L2005	Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright,

HCPCS	Long Description
	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, Prefabricated, Includes Fitting And Adjustment
L2136	Kafo, Fracture Orthosis, Femoral Fracture Cast Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment

HCPCS	Long Description
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
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

HCPCS	Long Description
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
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

HCPCS	Long Description
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
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,

HCPCS	Long Description
	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 Supension, 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, 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

HCPCS	Long Description
	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
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

HCPCS	Long Description
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
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

HCPCS	Long Description
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
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

HCPCS	Long Description
	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
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

HCPCS	Long Description
	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 propose to revise the existing DMEPOS Competitive Bidding Program (CBP) regulations in § 414.422(d) on change of ownership (CHOW) in recognition of the fact that CHOWs may occur on shorter timeframes than our regulations previously contemplated. We also propose to revise § 414.423(f) for the submission of a hearing request in notices of breach of contract.

B. Proposed Amendments

In § 414.422(d) we propose to revise the following amendments:

- We propose 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 propose 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 now recognize that the 60-day notice requirement is a bit onerous and as such we are proposing to remove paragraph (d)(1) in its entirety. We are also proposing changes to the rest of paragraph (d).

- We propose 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 propose 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 propose 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 would expedite CMS's determination on whether to allow transfer of the contract to the successor entity. We also propose that the successor entity must submit a novation agreement that states that it assumes all obligations under the contract.

- We propose 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 propose 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 would 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 propose 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 propose 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 would always result in a "successor" entity. In addition, we propose 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 propose to remove the acronym "i.e." and replace it with "that is."

In § 414.423(f)(2), we currently 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 propose 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. 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 solicit public comments on these amendments and request that when commenting on this section, commenters reference "DMEPOS CBP Proposed Amendments."

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

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[39], 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.

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

39 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

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.[40] Moreover, many ESRD facilities'

40 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-

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.

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.

2021-Technical-Specifications-.pdf.

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.[41]

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

41 Medicare Claims Processing Manual. Chapter 8 – Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims. (Rev. 4202, 01-18-19). Page 7/143.

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

CMS seeks input on options for improving the reporting of composite rate costs for the ESRD PPS. We believe 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 inform a refined case mix adjusted model for the ESRD PPS. We are seeking comments on, or elaborations of, the options presented and discussed during the TEP, described previously in section VIII.A.1.b.ii of this proposed rule, as well as novel approaches for improving the reporting of patient-level and facility-level costs that are not described here. 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. 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, CMS seeks 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.

Commenters are invited 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. CMS seeks 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 invite 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 is described in section VIII.A.1.b.v of this proposed 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.

CMS solicits comments and suggestions about how to best capture these costs. Some questions to consider include the following: 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.

CMS seeks input from stakeholders regarding the further identification of facility-level drivers of cost, especially those that affect the cost of composite rate services. Please 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

We also seek to gather responses to the following questions that arose during the TEP. 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.[42] As presented at the TEP, the data contractor's

42 Department of Health and Human Services. Centers for Medicare and Medicaid Services. Change Request 8978.

analysis of 2016 claims data revealed that approximately 40 percent of facilities were not reporting these items. We are requesting 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 medications. We are requesting 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 are also soliciting 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 solicit public comments for the request for information regarding data collection and request that when commenting on this section, commenters reference "RFI—Data Collection."

B. Wage Index Comment Solicitation

As discussed in section II.B.5.b of this proposed 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. We are soliciting comments on concerns stakeholders may have

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December 2, 2014 (pp 3-4). https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R200BP.pdf.

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 solicit public comments for the request for information regarding the wage index and request that when commenting on this section, commenters reference "RFI—Wage Index."

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." [43] 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 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

43 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.

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 said 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 said 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 said 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 said 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.[44] 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.

2. 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

44 https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000311.asp.

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.[45] 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.[46] 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.[47]

Because section 1847(b)(10)(A) of the Act now requires the use of "multiple sources of data," we are requesting 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 are requesting 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 are therefore requesting 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 are seeking data that:

- Has a sufficient sample size, and is unbiased and credible;
- 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

45 https://oig.hhs.gov/oei/reports/oei-04-18-00440.pdf.
46 https://oig.hhs.gov/oei/reports/oei-04-18-00441.pdf.

are not exclusively sold by a single retailer from such markets.

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. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Using the following format describe the information collection requirements that are in each section.

B. Requirements in Regulation Text

In sections II.B.1, II.B.2 and II.B.3 of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2020. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following is a discussion of these information collections.

1. ESRD QIP - Wage Estimates

To derive 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.[48] 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.

48 https://www.bls.gov/oes/current/oes292071.htm

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 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 proposed 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 proposed 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 would take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 750 hours (300 facilities 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 would 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 proposed in this proposed rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-1289).

In section IV.B.7 of this proposed rule, we propose to 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 to adopt the NHSN validation study as a permanent feature of the ESRD QIP. Under this methodology, we would select 300 facilities for participation in the PY 2023 validation study. A CMS contractor would 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 would 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 would submit these data, we estimate that the aggregate cost of the NHSN data validation each year would 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 proposed in this proposed 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 are not proposing any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2022 or PY 2023. However, we have 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 this proposed rule, we did not use a rounded estimate of the time needed to complete data entry for CROWNWeb reporting. As a result of these changes in the methodology, we estimate that the PY 2022 burden is $205 million (or 4.8 million hours), and the net incremental burden from PY 2022 to PY 2023 is $0 (or 0 hours).

X. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2020. The proposed 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 proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to ESRD patients.

b. AKI

This rule also proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2020 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c ESRD QIP

This rule proposes to implement requirements for the ESRD QIP, including proposals to modify the scoring methodology for the NHSN Dialysis Event reporting measure beginning with the PY 2022 ESRD QIP; a proposal to convert the STrR clinical measure to a reporting measure; and a proposal to convert the NHSN validation study into a permanent feature of the program using the methodology finalized for the PY 2022 NHSN validation study. In addition, we are proposing to establish CY 2021 and CY 2019 as the performance period and baseline period, respectively, for the PY 2023 ESRD QIP for all measures. For future ESRD QIP payment years, we propose to 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 proposes to establish a gap-filling methodology.

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

This rule proposes 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 proposed rule would 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 proposed revisions to the ESRD PPS would 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 proposal to change 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 our proposals to refine the TDAPA eligibility criteria, condition the TDAPA on ASP data availability, and provide a transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies. The fiscal impact of these proposals cannot be determined due to the uniqueness of the new renal dialysis drugs and biological products and new renal dialysis equipment and supplies and their costs.

b. AKI

We are estimating approximately $42 million that would 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 proposed in this proposed rule would 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 proposed policy changes described earlier, including the proposed changes to the scoring methodology for the NHSN Dialysis Event reporting measure and the proposed 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 would result in an overall impact of $219 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule, which includes an estimated $205 million in information collection burden and an additional $14 million in estimated payment reductions across all facilities, for PY 2022.

For PY 2023, we estimate that the proposed revisions to the ESRD QIP would result in

an overall impact of $219 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule, which includes a $14 million in estimated payment reductions across all facilities.

d. DMEPOS

i. Establishing Payment Amounts for New DMEPOS Items and Services

This rule proposes to establish a gap-filling methodology for new items and services. The fiscal impact of establishing payment amounts of new items based on the proposed gap-filling methodology cannot be determined due to the uniqueness of new items and their costs.

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

While these adjustments would 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 proposes 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 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 proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the 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 proposed 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 proposed rule. For each entity that reviews this proposed rule, the estimated cost is $110.00. Therefore, we estimate that the total cost of reviewing this proposed 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 proposed rule, we used CY 2018 data from the Part A and Part B Common Working Files as of February 15, 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 proposed rule. Table 11 shows the impact of the estimated CY 2020 ESRD payments compared to estimated payments to ESRD facilities in CY 2019.

TABLE 11: Impact of Proposed Changes in Payment to ESRD Facilities for CY 2020 Proposed Rule

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 2020 Changes in TDAPA (F)	Effect of Total 2020 Proposed Changes (G)
All Facilities	7,386	44.6	0.3%	0.0%	1.7%	-0.4%	1.6%
Type							
Freestanding	6,995	42.7	0.3%	0.0%	1.7%	-0.4%	1.5%
Hospital based	391	1.9	0.6%	0.0%	1.7%	-0.3%	1.9%
Ownership Type							
Large dialysis organization	5,603	34.5	0.3%	0.0%	1.7%	-0.4%	1.5%
Regional chain	927	5.7	0.3%	0.1%	1.7%	-0.5%	1.6%
Independent	512	2.9	0.3%	-0.1%	1.7%	-0.4%	1.5%
Hospital based[1]	305	1.5	0.6%	0.0%	1.7%	-0.3%	1.9%
Unknown	39	0.0	0.5%	0.0%	1.7%	-0.5%	1.7%
Geographic Location							
Rural	1,285	6.5	0.3%	0.3%	1.7%	-0.4%	1.8%
Urban	6,101	38.2	0.3%	0.0%	1.7%	-0.4%	1.5%
Census Region							
East North Central	1,188	6.1	0.3%	-0.1%	1.7%	-0.4%	1.5%
East South Central	587	3.3	0.3%	0.1%	1.7%	-0.5%	1.5%
Middle Atlantic	806	5.4	0.3%	-0.2%	1.7%	-0.4%	1.4%
Mountain	409	2.3	0.2%	0.1%	1.7%	-0.3%	1.7%
New England	198	1.4	0.3%	-0.4%	1.7%	-0.4%	1.2%
Pacific[2]	870	6.4	0.3%	0.0%	1.7%	-0.3%	1.7%
Puerto Rico and Virgin Islands	47	0.3	0.1%	0.3%	1.7%	-0.3%	1.7%
South Atlantic	1,699	10.5	0.3%	-0.1%	1.7%	-0.5%	1.4%
West North Central	508	2.2	0.4%	0.4%	1.7%	-0.4%	2.1%
West South Central	1,074	6.6	0.3%	0.1%	1.7%	-0.5%	1.6%
Facility Size							
Less than 4,000	1,206	2.5	0.3%	0.1%	1.7%	-0.4%	1.7%

treatments							
4,000 to 9,999 treatments	2,644	11.9	0.3%	0.1%	1.7%	-0.4%	1.6%
10,000 or more treatments	3,159	29.8	0.3%	0.0%	1.7%	-0.5%	1.5%
Unknown	377	0.5	0.4%	0.0%	1.7%	-0.4%	1.7%
Percentage of Pediatric Patients							
Less than 2%	7,288	44.3	0.3%	0.0%	1.7%	-0.4%	1.6%
Between 2% and 19%	38	0.2	0.3%	0.0%	1.7%	-0.4%	1.6%
Between 20% and 49%	14	0.0	0.2%	-0.1%	1.7%	-0.1%	1.8%
More than 50%	46	0.0	0.2%	-0.1%	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 proposed changes to the outlier payment policy described in section II.B.5.c of this proposed 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 0.3 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2020 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2020 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.4 percent decrease to a 0.4 percent increase due to these proposed updates in the wage indices.

Column E shows the effect of the proposed CY 2020 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.7 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2020 of 2.1 percent and the proposed MFP adjustment of 0.4 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 proposed outlier policy changes, the proposed wage index floor, payment rate update, and proposed 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 2.1 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 proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2020 would be approximately $11.1 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.7 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 proposed 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 $50 million.

e. Alternatives Considered

i. Eligibility criteria for the TDAPA

In section II.B.1 of this proposed rule, we proposed 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 proposed rule, we proposed to provide a transitional add-on payment adjustment to support the use of 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 was lacking for many items and did not address the upcoming new and innovative renal dialysis equipment and supplies that we expect to be forthcoming with the KidneyX program.

2. Proposed 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 proposed rule, we used CY 2018 data from the Part A and Part B Common Working Files as of February 15, 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 proposed rule. Table 12 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 12: Impact of Proposed Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2020 Proposed Rule

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 Proposed Changes (E)
All Facilities	4,372	172.7	-0.1%	1.7%	1.7%
Type					
Freestanding	4,257	168.8	-0.1%	1.7%	1.7%
Hospital based	115	3.9	0.1%	1.7%	1.8%
Ownership Type					
Large dialysis organization	3,600	135.0	-0.0%	1.7%	1.7%
Regional chain	526	25.5	-0.1%	1.7%	1.6%
Independent	171	9.9	-0.1%	1.7%	1.6%
Hospital based[1]	68	2.2	0.1%	1.7%	1.8%
Unknown	7	0.1	0.3%	1.7%	2.0%
Geographic Location					
Rural	772	30.5	0.3%	1.7%	2.0%
Urban	3,600	142.2	-0.1%	1.7%	1.6%
Census Region					
East North Central	790	33.0	-0.0%	1.7%	1.7%
East South Central	372	16.2	0.2%	1.7%	1.9%
Middle Atlantic	452	20.0	-0.3%	1.7%	1.4%
Mountain	267	11.0	0.0%	1.7%	1.7%
New England	138	5.0	-0.4%	1.7%	1.3%
Pacific[2]	513	21.5	-0.1%	1.7%	1.6%
Puerto Rico and Virgin Islands	2	0.0	0.4%	1.7%	2.1%
South Atlantic	1,008	41.3	-0.1%	1.7%	1.6%
West North Central	278	8.3	0.4%	1.7%	2.1%
West South Central	552	16.4	0.0%	1.7%	1.8%
Facility Size					
Less than 4,000 treatments	493	15.9	-0.1%	1.7%	1.6%
4,000 to 9,999 treatments	1,646	61.4	0.0%	1.7%	1.7%

10,000 or more treatments	2,108	92.0	-0.1%	1.7%	1.6%
Unknown	125	3.4	0.1%	1.7%	1.8%
Percentage of Pediatric Patients					
Less than 2%	4,371	172.7	-0.1%	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	-1.6%	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 proposed CY 2020 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments of a 0.1 percent decrease due to these proposed updates in the wage indices.

Column D shows the effect of the proposed CY 2020 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.7 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2020 of 2.1 percent and the MFP adjustment of 0.4 percent.

Column E reflects the overall impact, that is, the effects of the proposed wage index floor and payment rate update. We expect that overall ESRD facilities would experience a 1.7 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 0.0 percent to 2.1 percent 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 proposing

to update 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 proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $42 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 would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. We are proposing in this proposed rule to convert the STrR clinical measure to a reporting measure, and also to 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).[49]

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP would 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 7,099 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 21.9 percent or 1,506 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 1,506 facilities expected to receive a payment reduction is approximately $13,905,923.02. Facilities that do not receive a TPS do not receive a payment reduction.

Table 13 shows the overall estimated distribution of payment reductions resulting from

[49] We are proposing to redesignate paragraph (d) as paragraph (e) in this proposed rule.

the PY 2022 ESRD QIP.

TABLE 13: Estimated Distribution of PY 2022 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,370	78.10%
0.5%	1,116	16.23%
1.0%	325	4.73%
1.5%	56	0.81%
2.0%	9	0.13%

*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 14) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 14. We also note that we are proposing in section IV.B.3.b of this proposed rule to convert the STrR measure from a clinical measure to a reporting measure.

TABLE 14: Data Used to Estimate PY 2022 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 2016-Dec 2016	Jan 2017-Dec 2017
SRR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
STrR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
SHR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
PPPW	Jan 2016-Dec 2016	Jan 2017-Dec 2017
Kt/V Dialysis Adequacy Comprehensive	Jan 2016-Dec 2016	Jan 2017-Dec 2017
VAT		
Standardized Fistula Ratio	Jan 2016-Dec 2016	Jan 2017-Dec 2017
%Catheter	Jan 2016-Dec 2016	Jan 2017-Dec 2017
Hypercalcemia	Jan 2016-Dec 2016	Jan 2017-Dec 2017

For all measures except SHR and STrR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were

required to have at least 5 at risk patients and 10 at risk patients, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2017 and 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 proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2017 through December 2017 times the estimated payment reduction percentage.

Table 15 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by 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 15: Impact of Proposed ESRD QIP Payment Reductions to ESRD Facilities for PY 2022

	Number of Facilities	Number of Treatments 2017 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,099	45.1	6,876	1,506	-0.14%
Facility Type:					
Freestanding	6,681	43.0	6,510	1,407	-0.13%
Hospital-based	418	2.2	366	99	-0.22%
Ownership Type:					
Large Dialysis	5,400	34.9	5,290	1,068	-0.12%
Regional Chain	881	5.7	848	192	-0.14%
Independent	485	2.9	454	165	-0.26%
Hospital-based (non-chain)	327	1.7	284	81	-0.24%
Unknown	6	0.0	0	0	-
Facility Size:					
Large Entities	6,281	40.6	6,138	1,260	-0.12%
Small Entities[1]	812	4.6	738	246	-0.25%
Unknown	6	0.0	0	0	-
Rural Status:					
1) Yes	1,271	6.5	1,231	119	-0.05%
2) No	5,828	38.6	5,645	1,387	-0.16%
Census Region:					
Northeast	968	7.0	930	205	-0.15%
Midwest	1,642	8.6	1,584	347	-0.14%
South	3,193	20.5	3,099	763	-0.15%
West	1,237	8.6	1,205	166	-0.08%
US Territories[2]	59	0.4	58	25	-0.30%
Census Division:					
Unknown	8	0.1	7	4	-0.42%
East North Central	1,145	6.3	1,107	286	-0.17%
East South Central	572	3.3	562	116	-0.13%
Middle Atlantic	777	5.5	745	184	-0.16%
Mountain	400	2.3	390	39	-0.06%
New England	191	1.5	185	21	-0.07%
Pacific	837	6.4	815	127	-0.09%
South Atlantic	1,622	10.6	1,571	405	-0.16%
West North Central	497	2.3	477	61	-0.08%
West South Central	999	6.6	966	242	-0.16%
US Territories[2]	51	0.3	51	21	-0.28%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,246	2.1	1,060	193	-0.14%
4,000-9,999 treatments	2,666	11.9	2,656	439	-0.10%
Over 10,000 treatments	3,147	31.0	3,144	866	-0.17%
Unknown	40	0.2	16	8	-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 7,099 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 21.9 percent or 1,506 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 1,506 facilities expected to receive a payment reduction is approximately $13,905,923.02. 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 2023 ESRD QIP.

TABLE 16: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,370	78.10%
0.5%	1,116	16.23%
1.0%	325	4.73%
1.5%	56	0.81%
2.0%	9	0.13%

*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 16) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 17. We also note that we are proposing in section IV.B.3.b of this proposed rule to convert the STrR measure from a clinical measure to a reporting measure.

TABLE 17: 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

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 2016-Dec 2016	Jan 2017-Dec 2017
SRR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
STrR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
SHR	Jan 2016-Dec 2016	Jan 2017-Dec 2017
PPPW	Jan 2016-Dec 2016	Jan 2017-Dec 2017
Kt/V Dialysis Adequacy Comprehensive	Jan 2016-Dec 2016	Jan 2017-Dec 2017
VAT		
Standardized Fistula Ratio	Jan 2016-Dec 2016	Jan 2017-Dec 2017
%Catheter	Jan 2016-Dec 2016	Jan 2017-Dec 2017
Hypercalcemia	Jan 2016-Dec 2016	Jan 2017-Dec 2017

For all measures except SHR and STrR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 at-risk patients and 10 at-risk patients, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B and IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2017 and 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 proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2017 through December 2017 times the estimated payment reduction percentage.

Table 18 shows the estimated impact of the finalized 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 we are proposing 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 18: Impact of Proposed 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	7,099	45.1	6,876	1,506	-0.14%
Facility Type:					
Freestanding	6,681	43.0	6,510	1,407	-0.13%
Hospital-based	418	2.2	366	99	-0.22%
Ownership Type:					
Large Dialysis	5,400	34.9	5,290	1,068	-0.12%
Regional Chain	881	5.7	848	192	-0.14%
Independent	485	2.9	454	165	-0.26%
Hospital-based (non-chain)	327	1.7	284	81	-0.24%
Unknown	6	0.0	0	0	-
Facility Size:					
Large Entities	6,281	40.6	6,138	1,260	-0.12%
Small Entities[1]	812	4.6	738	246	-0.25%
Unknown	6	0.0	0	0	-
Rural Status:					
1) Yes	1,271	6.5	1,231	119	-0.05%
2) No	5,828	38.6	5,645	1,387	-0.16%
Census Region:					
Northeast	968	7.0	930	205	-0.15%
Midwest	1,642	8.6	1,584	347	-0.14%
South	3,193	20.5	3,099	763	-0.15%
West	1,237	8.6	1,205	166	-0.08%
US Territories[2]	59	0.4	58	25	-0.30%
Census Division:					
Unknown	8	0.1	7	4	-0.42%
East North Central	1,145	6.3	1,107	286	-0.17%
East South Central	572	3.3	562	116	-0.13%
Middle Atlantic	777	5.5	745	184	-0.16%
Mountain	400	2.3	390	39	-0.06%
New England	191	1.5	185	21	-0.07%
Pacific	837	6.4	815	127	-0.09%
South Atlantic	1,622	10.6	1,571	405	-0.16%
West North Central	497	2.3	477	61	-0.08%
West South Central	999	6.6	966	242	-0.16%
US Territories[2]	51	0.3	51	21	-0.28%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,246	2.1	1,060	193	-0.14%
4,000-9,999 treatments	2,666	11.9	2,656	439	-0.10%
Over 10,000 treatments	3,147	31.0	3,144	866	-0.17%
Unknown	40	0.2	16	8	-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 would contribute approximately $13,905,923.02 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 19 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 19: Estimated Payment Reductions Payment Years 2018 through 2023

Payment year	Estimated payment reductions
PY 2023	$13,905,923.02
PY 2022	$13,905,923.02
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 would have a positive economic impact on suppliers by making the pricing of new items more easily understood and encourage innovation. The cost of this proposal cannot be estimated as these new items are not identified.

(2) Effects on the Medicare Program

This proposal 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 proposal has an indeterminable cost to the Medicare beneficiary due to the unpredictable nature of future new items. Likewise, this proposal 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 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 would have a negative economic impact on suppliers by lowering fees. The savings of this proposal 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 would have a positive economic impact on the Medicare Program by lowering fees and achieving savings. The savings of this proposal

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 would have a positive economic impact on Medicare beneficiaries by lowering fees, therefore resulting in lower coinsurance for such items. The savings of this proposal cannot be estimated as these new items are not identified.

(4) Alternatives Considered

An alternative we considered was to continue not adjusting payment amounts for new items based on revised supplier and commercial price lists. This would have created, in some cases, what we consider to be unreasonable fee schedule amounts and a cost to the program and beneficiaries.

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

This rule proposes 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 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 20, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 20: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI	
Category	**Transfers**
Annualized Monetized Transfers	$160 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$50 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2022	
Category	**Transfers**
Annualized Monetized Transfers	-$14 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2023	
Category	**Transfers**
Annualized Monetized Transfers	-$14 million
From Whom to Whom	Federal government to ESRD providers

In accordance with the provisions of Executive Order 12866, this proposed 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 $38.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at http://www.sba.gov/content/small-business-size-standards (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 11. Using the definitions in this ownership category, we consider 512 facilities that are independent and 305 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.9 percent increase in payments for CY 2020. An independent facility (as defined by ownership type) is also estimated to receive a 1.5 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 $42 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,506 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2023 ESRD QIP, 246 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 Proposed QIP Payment Reductions to ESRD Facilities for PY 2023"). We estimate that the payment reductions would average approximately $9,233.68 per facility across the 1,506 facilities receiving a payment reduction, and $8,850.82 for each small entity facility. We also estimate that there are 812 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.25 percent in CY 2023.

The DMEPOS provisions in this proposed 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 proposed 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 proposed 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 proposed 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 solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of

the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 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 proposed 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 proposed rules do not include any mandates that would impose spending costs on state, local, or Tribal governments in the aggregate, or by the private sector, of $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 proposed 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 proposed rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

XII. 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 proposes to amend 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 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. 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 would be communicated to the public via a 60-day **Federal Register** document and posted to the CMS website. 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) Date.

(E) Practitioner Name or National Provider Identifier (NPI).

(F) 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 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; and sec. 124 of Public Law 106-113, 113 Stat. 1501A-332; sec. 3201 of Public Law 112-96, 126 Stat. 156; sec. 632 of Public Law 112-240, 126 Stat. 2354; sec. 217 of Public Law 113-93, 129 Stat. 1040; and sec. 204 of Public Law 113-295, 128 Stat. 4010; and sec. 808 of Public Law 114-27, 129 Stat. 362.

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 addition reads 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 fully with the requirements in paragraph (d) 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 revising paragraphs (b) and (c) and adding paragraph (d) and (e) to 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 is 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), as amended November 14, 2018, at 83 FR 57070, and effective January 1, 2020;

c. By revising paragraph (c) introductory text, as amended November 14, 2018, at 83 FR 57070, and effective January 1, 2020; 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 this paragraph (e)(2).

(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 this paragraph (e)(2), 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. The 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 a 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) 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 the Food and Drug Administration (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) 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.

(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 paragraphs (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) through (d) 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) or (d) 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.

(d) *Use of technology assessments.* (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 technology assessments, performed by biomedical engineers, certified orthotists and prosthetists, and others knowledgeable about the cost of DMEPOS items and services, to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts to determine a pricing percentage as described in paragraph (d)(2) of this section for the purpose of establishing the fee schedule amounts for the new code.

(2) A pricing percentage is established based on the results of the technology assessment and is used to establish the fee schedule amounts for the new code(s). The pricing percentages are applied to the fee schedule amounts for HCPCS codes with existing fee schedule amounts to calculate the fee schedule amounts for new HCPCS codes without a fee schedule pricing history. Technology assessments would be used whenever it is necessary to determine the relative cost of a new item compared to items from the fee schedule base period in order to establish fee schedule amounts 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.

13. Section 414.234 is amended --

a. In paragraph (a) by adding in alphabetical order a definition for "Required Prior Authorization List";

b. By revising the heading of paragraph (b) and revising paragraphs (b)(1) and (2),

(b)(3)(i) through (iii), and (b)(4) and (6);

c. By revising paragraphs (c)(1)(i) and (ii), (d)(1) introductory text and (d)(1)(i), and (e)(3) and (4); and

d. 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) through (d) 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) or (d) 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.

(d) *Use of technology assessments.* (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 technology assessments, performed by biomedical engineers, certified orthotists and prosthetists, and others knowledgeable about the cost of DMEPOS items and services, to determine the relative cost of the items and services described by the new codes to items and services with existing fee schedule amounts to determine a pricing percentage as described in paragraph (d)(2) of this section for the purpose of establishing the fee schedule amounts for the new code.

(2) A pricing percentage is established based on the results of the technology assessment and is used to establish the fee schedule amounts for the new code(s). The pricing percentages are applied to the fee schedule amounts for HCPCS codes with existing fee schedule amounts to calculate the fee schedule amounts for new HCPCS codes without a fee schedule pricing history.

Technology assessments would be used whenever it is necessary to determine the relative cost of a new item compared to items from the fee schedule base period in order to establish fee schedule amounts 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.

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.

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Dated: June 21, 2019.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: July 24, 2019.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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