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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS-1732-P]

RIN 0938-AU08

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

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) 2021. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this rule proposes to update requirements for the ESRD Quality Incentive Program (QIP).

DATES: To be assured consideration, comments must be submitted at one of the addresses provided below, no later than September 4, 2020.

ADDRESSES: In commenting, please refer to file code CMS-1732-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-1732-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-1732-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.

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.

I. Executive Summary

A. Purpose

B. Summary of the Major Provisions

C. Summary of Cost and Benefits

II. Calendar Year (CY) 2021 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

B. Provisions of the Proposed Rule

C. Proposed Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2021 Payment

III. Calendar Year (CY) 2021 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. Background

B. Proposed Annual Payment Rate Update for CY 2021

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

A. Background

B. Proposed Updates to Requirements Beginning with the PY 2023 ESRD QIP

C. Proposals for the PY 2023 ESRD QIP

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

B. Requirements in Regulation Text

C. Additional Information Collection Requirements

VI. Response to Comments

VII. Economic Analyses

A. Regulatory Impact Analysis

B. Detailed Economic Analysis

C. Accounting Statement

D. Regulatory Flexibility Act Analysis

E. Unfunded Mandates Reform Act Analysis

F. Federalism Analysis

G. Reducing Regulation and Controlling Regulatory Costs

H. Congressional Review Act

VIII. Files Available to the Public via the Internet

Regulations Text

I. Executive Summary

A. Purpose

This 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), and the ESRD Quality Incentive Program (QIP).

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

On January 1, 2011, we implemented the ESRD 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 2021.

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 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 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 2021.

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 payment years (PY) 2023 and 2024 ESRD QIP.

B. Summary of the Major Provisions

1. ESRD PPS

- Update to the ESRD PPS base rate for CY 2021: The proposed CY 2021 ESRD PPS base rate is \$255.59. This proposed amount reflects the application of the wage index budget-neutrality adjustment factor (.998652), the proposed addition to the base rate of \$12.06 to include calcimimetics, and a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.8 percent), equaling \$255.59 ($(\$239.33 \times .998652) + \$12.06 \times 1.018 = \$255.59$).

- 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 2021, we are proposing to update the wage index values based on the latest available data.

- New Office of Management and Budget (OMB) delineations and 2-year transition

policy: We are proposing to adopt the Office of Management and Budget (OMB) delineations as described in the September 14, 2018 OMB Bulletin No. 18-04, beginning with the CY 2021 ESRD PPS wage index. In addition, we are proposing to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would be phased in over 2 years, such that the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022.

- 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 2021 using CY 2019 claims data. Based on the use of the latest available data, the proposed FDL amount for pediatric beneficiaries would increase from \$41.04 to \$47.73, and the MAP amount would increase from \$32.32 to \$33.08, as compared to CY 2020 values. For adult beneficiaries, the proposed FDL amount would increase from \$48.33 to \$133.52, and the MAP amount would increase from \$35.78 to \$54.26. The 1.0 percent target for outlier payments was not achieved in CY 2019. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent.

- Inclusion of calcimimetics in the ESRD PPS base rate: We are proposing the methodology for modifying the ESRD PPS base rate to include calcimimetics in the ESRD

PPS bundled payment. Using the proposed methodology based on the latest available data, we are proposing to add \$12.06 to the ESRD PPS base rate beginning in CY 2021.

- Changes to the eligibility criteria for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES): We are proposing changes to the transitional add-on payment for new and innovative equipment and supplies (TPNIES) eligibility criteria in light of the changes implemented in CY 2020 to provide biannual coding cycles for code applications for new Healthcare Common Procedure Coding System (HCPCS) codes for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services. We are proposing that for purposes of eligibility for the TPNIES, a complete HCPCS code application must be submitted by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website. In addition, the Food and Drug Administration (FDA) marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. We are also proposing to define “new” for purposes of the TPNIES policy as within 3 years beginning on the date of the FDA marketing authorization.

- Expansion of the TPNIES to include new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient: We are proposing to expand eligibility for the TPNIES to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. As with other renal dialysis equipment and supplies potentially eligible for the TPNIES, CMS would evaluate the

application to determine whether the home dialysis machine represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries, and meets the other requirements under § 413.236(b). We are proposing additional steps the Medicare Administrative Contractors (MACs) would follow to establish the basis payment of the TPNIES for these capital-related assets that are home dialysis machines when used in the home. We would pay 65 percent of the MAC-determined pre-adjusted per treatment amount for 2-calendar years. We are proposing that after the 2-year TPNIES period ends, the home dialysis machines would not become eligible outlier services and no change would be made to the ESRD PPS base rate.

- Low-Volume Payment Adjustment (LVPA): We are proposing to hold harmless ESRD facilities that would otherwise qualify for the LVPA but for a temporary increase in dialysis treatments furnished in 2020 due to the Public Health Emergency (PHE) for the coronavirus disease 2019 (COVID-19) pandemic. For purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, we are proposing to only consider total dialysis treatments furnished for any 6 months of a facility's cost-reporting period ending in 2020; ESRD facilities would select those 6 months (consecutive or non-consecutive) during which treatments would be counted for purposes of the LVPA determination. We are proposing that ESRD facilities would attest that their total dialysis treatments for those 6 months of their cost-reporting period ending in 2020 are less than 2,000 and that, although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID-19 PHE. MACs would annualize the total dialysis treatments for the total

treatments reported in those 6 months by multiplying by 2. ESRD facilities would be expected to provide supporting documentation to the MACs upon request.

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

We are proposing to update the AKI payment rate for CY 2021. The proposed CY 2021 payment rate is \$255.59, which is the same as the base rate proposed under the ESRD PPS for CY 2021.

3. ESRD QIP

We propose to update the scoring methodology used to calculate the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months, and to reduce the number of records that facilities selected for National Health Safety Network (NHSN) validation are required to submit. This rule also clarifies the timeline for facilities to make changes to their NHSN Bloodstream Infection (BSI) clinical measure and NHSN Dialysis Event reporting measure data for purposes of the ESRD QIP. This rule also provides estimates for the performance standards and payment reductions that would apply for PY 2023.

This rule does not propose any new requirements beginning with the PY 2024 ESRD QIP.

C. Summary of Costs and Benefits

In section VII 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 VII.B of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2021 compared to estimated payments in CY 2020. The overall impact of the proposed CY 2021 changes is projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.4 percent decrease in payments compared with freestanding facilities with an estimated 1.6 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$190 million in CY 2021 compared to CY 2020. This reflects a \$230 million increase from the payment rate update, a \$40 million increase due to the updates to the outlier threshold amounts, and an \$80 million decrease from the proposed addition to the ESRD PPS base rate to include calcimimetics and no longer provide the transitional drug add-on payment adjustment (TDAPA) for calcimimetics. As a result of the projected 1.6 percent overall payment increase, we estimate there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2021, which translates to approximately \$40 million.

These figures do not reflect estimated increases or decreases in expenditures based on our proposal to expand the TPNIES to include certain capital-related assets that are home dialysis machines when used in the home. The fiscal impact of this proposal cannot be determined because these new and innovative home dialysis machines are not yet identified and would vary in uniqueness and costs.

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

The impact chart in section VII.B of this proposed rule displays the estimated change in proposed payments to ESRD facilities in CY 2021 compared to estimated payments in CY 2020. The overall impact of the proposed CY 2021 changes is projected to be a

6.9 percent increase in payments for individuals with AKI. Hospital-based and freestanding ESRD facilities both have an estimated 6.9 percent increase in payments for individuals with AKI. The overall impact reflects the effects of the updated wage index, the proposed addition to the ESRD PPS base rate of \$12.06 to include calcimimetics in the ESRD PPS bundled payment, and the payment rate update.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the proposed CY 2021 ESRD PPS base rate would increase by \$5 million in CY 2021 compared to CY 2020.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the PY 2023 ESRD QIP would be approximately \$221 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The \$221 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate would be approximately \$205 million, and \$16 million in estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2024 ESRD QIP would be approximately \$221 million as a result of the policies we have previously finalized. The \$221 million figure for PY 2024 includes costs associated with the collection of information requirements, which we estimate would be approximately \$205 million.

II. Calendar Year (CY) 2021 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 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 provides for a transitional drug add-on payment adjustment (TDAPA) for certain new renal dialysis drugs and biological products (§ 413.234(c)).

The ESRD PPS also provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

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 8, 2019, 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) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements,” referred to as the CY 2020 ESRD PPS final rule. In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy, for CY 2020. We also finalized revisions to the eligibility criteria for the TDAPA for certain new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, modified the basis of payment for the TDAPA for calcimimetics, established a new policy to condition the TDAPA payment on our receipt of average sales price (ASP) data, established the TPNIES to support ESRD facilities in their uptake of certain new and innovative renal dialysis equipment and supplies, and discontinued the erythropoiesis-stimulating agent (ESA) monitoring policy under the ESRD PPS. For further detailed information regarding these updates, see 84 FR 60648.

B. Provisions of the Proposed Rule

1. Inclusion of Calcimimetics into the ESRD PPS Bundled Payment

a. Background on Oral-Only Renal Dialysis Drugs

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and clause (iii) of such section states that these services include other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

We interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than erythropoiesis-stimulating agents (ESAs) and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B), such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs and biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at § 413.171 as including other drugs and biological products that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011 under Title XVIII of the Act, including drugs and biological products with only an oral form. We further described oral-only drugs as

those that have no injectable equivalent or other form of administration (75 FR 49038 through 49039). Although we included oral-only renal dialysis service drugs and biological products in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), we noted that the only oral-only drugs and biological products that we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only renal dialysis service drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form is incorporated into the PPS payment rates effective January 1, 2014. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed the coverage under Medicare to continue under Part D.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.176(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this delay by revising the effective date at § 413.174(f)(6) from January 1, 2014 to

January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 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.

On December 19, 2014, ABLE was enacted. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2025. We implemented this delay in the CY 2016 ESRD PPS final rule (80 FR 69027 through 69028) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2024 to January 1, 2025. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025.

b. ESRD PPS Drug Designation Process and Calcimimetics

In addition to delaying implementation of the policy for oral-only renal dialysis service drugs and biological products under the ESRD PPS, discussed previously in this proposed rule, PAMA included section 217(c), which 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 (IV) products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount to reflect the costs of furnishing that product.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. We defined an oral-only drug at § 413.234(a) to mean a drug or biological with no injectable equivalent or other form of administration other than an oral form.

Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized that the drug designation process is dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the PPS in 2011. We provided a detailed discussion on how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011 (80 FR 69013 through 69015).

We explained that, in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), in order to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated in the CY 2011 ESRD PPS final rule that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

In the CY 2016 ESRD PPS final rule, we also explained that, in CY 2011 ESRD PPS rulemaking, we grouped the injectable and IV drugs and biological products into ESRD PPS functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. The ESRD bundled market

basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

We established in § 413.234(b)(2) that, if the new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA described in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

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

We also established, in the CY 2016 ESRD PPS final rule (80 FR 69024 through 69027), an exception to the drug designation process for calcimimetics. We noted that in the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), the only oral-only drugs and biological products we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that we defined these oral-only drugs as renal dialysis services in our regulations at § 413.171

(75 FR 49044), delayed the Medicare Part B payment for these oral-only drugs until CY 2014 at § 413.174(f)(6), and continued to pay for them under Medicare Part D. We explained in the CY 2016 ESRD PPS final rule that, under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category, so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and stated that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the ESRD PPS base rate to account for these drugs. Instead, we finalized a policy that once the injectable or IV phosphate binder or calcimimetic is FDA approved and has a Healthcare Common Procedure Coding System (HCPCS) code, we will issue a change request to pay for all forms of the phosphate binder or calcimimetic using the TDAPA based on the payment methodologies under section 1847A of the Act, which could include ASP + 6 percent, for a period of at least 2 years. We explained in the CY 2016 ESRD PPS final rule that this will allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment. We stated that during this period we will not pay outlier payments for these drugs. We further stated that at the end of the 2 or more years, we will adopt the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment through notice-and-comment rulemaking.

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule, we issued a change request to implement

payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA. 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.

In CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, for example, we revised regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration, that is, new injectable, IV, oral, or other form or route of administration (83 FR 56932). In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories (83 FR 56942 through 56943). We also revised § 413.234(c) to reflect that we 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 explained that the 6 percent add-on to ASP has been used to cover administrative and overhead costs, however, the ESRD PPS base rate includes dollars for administrative complexities and overhead costs for drugs and biological products, so we believe ASP + 0 is a reasonable basis for the TDAPA under the ESRD PPS (83 FR 56943 through 56944). For circumstances when ASP data is not available, we finalized that the TDAPA is based on wholesale acquisition cost (WAC) + 0 and, when WAC is not available, the TDAPA is based on the drug manufacturer's invoice (83 FR 56948). We also finalized a revision to § 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 (83 FR 56948). These provisions all had an effective date of January 1, 2020.

In the CY 2020 ESRD PPS final rule, we made several additional revisions to the ESRD PPS drug designation process regulations at § 413.234. For example, we revised § 413.234(b) and added paragraph (e) to codify certain eligibility criteria changes for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. That is, we excluded certain drugs from being eligible for the TDAPA, effective January 1, 2020 (84 FR 60672). Specifically, as detailed in the CY 2020 ESRD PPS final rule (85 FR 60565 through 60673), we excluded generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the “parent NDA” is a Type 3, 5, 7 or 8— from being eligible for the TDAPA. We also established at § 413.234(c) a policy to condition application of the TDAPA on our receipt of ASP data (84 FR 60681).

In the CY 2020 ESRD PPS final rule (84 FR 60673), we also discussed the duration of payment of the TDAPA for calcimimetics and changed the basis of the TDAPA for such products. We stated that in accordance with our policy for calcimimetics under the drug designation process, we would pay for calcimimetics using the TDAPA for a minimum of 2 years until sufficient claims data for rate setting analysis is available for these products. We noted that at the time of the CY 2020 ESRD PPS proposed rule we were still in the process of collecting utilization claims data for both the oral and injectable form of calcimimetics. Therefore, in the CY 2020 ESRD PPS proposed rule, we stated that we would continue to pay for calcimimetics using the TDAPA in CY 2020 (84 FR 38347).

However, we also noted in the CY 2020 ESRD PPS proposed rule that we had provided the TDAPA for calcimimetics at ASP + 6 percent for 2-full years (that is, January 1, 2018 through December 31, 2019), and we believed that was sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. We noted that it was clear that ESRD facilities were furnishing calcimimetics because payment for them using the TDAPA had increased Medicare expenditures by \$1.2 billion in CY 2018 (84 FR 60673). We explained that one of the rationales for the 6 percent add-on to ASP was to cover administrative and overhead costs, however, the ESRD PPS base rate has dollars included for administrative complexities and overhead costs for drugs and biological products. Therefore, in the CY 2020 ESRD PPS final rule, we finalized a revision to § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, would be 100 percent of ASP (84 FR 60676). We explained this policy change provided a balance between supporting ESRD facilities in their uptake of these products and limiting the financial burden that increased payments place on beneficiaries and Medicare expenditures. We also noted that this policy 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).

c. Proposed Methodology for Modifying the ESRD PPS Base Rate to Account for Calcimimetics in the ESRD PPS Bundled Payment

As we discussed previously in section II.B.1.b of this proposed rule, under § 413.234(d), calcimimetics were no longer considered to be an oral-only drug once FDA approved an injectable calcimimetic in 2017. We have paid for calcimimetics under the ESRD PPS using the TDAPA since January 1, 2018. We stated in the CY 2016 ESRD PPS final rule that for

calcimimetics—for which there is an ESRD PPS functional category, but no money is in the base rate—we will utilize the TDAPA to collect utilization data before adding this drug to the ESRD PPS base rate. This will allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drug, as well as payment patterns and beneficiary co-pays, and at the end of the 2 or more years, we will adopt the methodology for including this drug in the ESRD PPS bundled payment through notice-and-comment rulemaking.

We believe we have collected sufficient claims data for a rate setting analysis for calcimimetics. Specifically, we have collected robust claims data for 2-full years and analyzed the utilization of every generic and brand name oral calcimimetic, along with the utilization of the injectable calcimimetic. We monitored the ASP data available during the specific utilization periods. Our overall analysis of ESRD claims data for CYs 2018 and 2019 indicated an increase in the utilization of the oral generic calcimimetic drugs with a steep decline in the brand-name oral calcimimetic. This resulted in an overall decrease in ASP as the generic calcimimetic drugs entered the market in late 2018 and the beginning of 2019, since the generic version is less expensive than the brand-name version. Since beneficiaries have a 20 percent co-pay under the ESRD PPS, a decrease in the payment for calcimimetics results in a decrease in the beneficiary co-pay.

Therefore, we believe that we are at the step of the ESRD PPS drug designation process where we propose to adopt the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment through CY 2021 notice-and-comment rulemaking. That is, in this proposed rule, we are proposing to add a per treatment amount to the ESRD PPS base rate to include the calcimimetics in the ESRD PPS bundled payment amount.

In developing the proposed methodology for including calcimimetics into the ESRD PPS

base rate, we considered the methodology that we used when we included Part B drugs and biological products in the ESRD PPS base rate as part of our implementation of the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49074 through 49079), we discussed how we established which renal dialysis drugs and biological products would be reflected in the ESRD PPS base rate. We used the utilization of those drugs and biological products from Medicare claims data and applied ASP + 6 percent to establish the price for each drug. Then we inflated each drug's price to 2011 using the Producer Price Index (PPI) for prescription drugs.

In addition, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49064), we established a dialysis treatment as the unit of payment. Consistent with the approach we used initially to include drugs and biological products into the ESRD PPS base rate and the ESRD PPS unit of payment, we are proposing a similar methodology in this rule to calculate a one-time modification to the ESRD PPS base rate on a per-treatment basis to account for calcimimetics. We believe the proposed methodology is similar to the CY 2011 approach because we would determine utilization of the drug, in this case, calcimimetics, along with the payment amounts associated with each oral and injectable form based on the ASP + 0 instead of ASP + 6, as discussed in the CY 2020 ESRD PPS final rule.

The following sections discuss each element of our proposed methodology in detail. As an overview, we are proposing to calculate a per-treatment amount for calcimimetics that would be added to the ESRD PPS base rate. We would apply the value from the most recent calendar quarter ASP calculations at 100 percent of ASP (that is, ASP + 0) available to the public for calcimimetics to the utilization data for calcimimetics from CYs 2018 and 2019 Medicare ESRD claims data. This would provide the calcimimetic expenditure amount. We would divide the calcimimetic expenditure amount by the total number of hemodialysis-equivalent dialysis

treatments paid in CYs 2018 and 2019 under the ESRD PPS. We would reduce this average per treatment amount by 1 percent to account for the outlier policy, since calcimimetics would be ESRD outlier services eligible for outlier payments beginning January 1, 2021. We propose to add the resulting amount to the ESRD PPS base rate. We note that this amount will stay in the base rate and be subject to the annual updates (productivity adjusted market basket increase and application of wage index budget neutrality adjustment factor). Under this proposal, CMS would stop paying for these drugs using the TDAPA for dates of service on or after January 1, 2021.

We are proposing to revise our drug designation regulation at § 413.234, by adding paragraph (f), to describe the methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics, including the data sources and the steps we would take to calculate a per treatment amount. We propose, for dates of service on or after January 1, 2021, calcimimetics would no longer be paid for under the ESRD PPS using the TDAPA (§ 413.234(c)) and would be paid for through the ESRD PPS base rate and eligible for outlier payments as ESRD outlier services under § 413.237.

We note that the methodology proposed in this rule is only for modifying the ESRD PPS base rate to include calcimimetic drugs. We stated in the CY 2016 ESRD PPS final rule (80 FR 69022) that the TDAPA will be paid for a minimum of 2 years, during which time we will gather utilization data. At the end of that time, the drug will be included within its new functional category and the base rate may or may not be modified to account for the cost of the drug, depending upon what the utilization data show. Accordingly, our policy is to propose and adopt the methodology for including any future eligible new renal dialysis drugs and biological products into the ESRD PPS base rate through notice-and-comment rulemaking.

(1) Determining Utilization of Calcimimetics

For use in the proposed calculation, we analyzed the utilization of both the oral and injectable forms of calcimimetics reported on the ESRD facility claims for CYs 2018 and 2019. ESRD facilities report this information to CMS on Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X. The oral calcimimetic is reported as HCPCS J0604 (Cinacalcet, oral, 1 mg, (for ESRD on dialysis)) and the injectable calcimimetic is reported as HCPCS J0606 (Injection, etelcalcetide, 0.1 mg), that is, one unit of J0604 is 1 mg, and one unit of J0606 is 0.1 mg. For purposes of this rate setting analysis, we consider utilization of calcimimetics as the units of the product furnished to an ESRD beneficiary.

For the CY 2018 utilization data for calcimimetics, we propose to use the latest available claims data based on the CY 2018 ESRD facility claims updated through June 30, 2019 (that is, claims with dates of service from January 1 through December 31, 2018, that were received, processed, paid, and passed to the National Claims History (NCH) File as of June 30, 2019) to calculate 2018 utilization. Claims that are received, processed, paid, and passed to the NCH file are considered to be “complete” because they have been adjudicated.

For the CY 2019 utilization data for calcimimetics, we propose to use the latest available claims data based on the CY 2019 ESRD facility claims to calculate 2019 utilization. For this proposed rule, the latest available CY 2019 ESRD facility claims used were updated through January 31, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH File as of January 31, 2020). For the CY 2021 ESRD PPS final rule, the latest available CY 2019 ESRD facility claims we would use for purposes of our final calculation would be updated through June 30, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH File as of June 30, 2020).

While we have continued to pay the TDAPA for calcimimetics for dates of service in CY 2020, we are not proposing to use utilization data from this period because practice patterns in CY 2020 have been altered due to the COVID-19 pandemic and the resulting impact on data is unknown at this time. However, our policy to continue paying for calcimimetics using the TDAPA in CY 2020 has allowed us to analyze 2 full years of adjudicated Medicare claims since CY 2019 claims include those claims from January 1, 2019 through December 31, 2019.

We solicit comments on the proposed use of CYs 2018 and 2019 claims data to determine the utilization of calcimimetics for purposes of calculating the proposed addition to the ESRD PPS base rate to account for calcimimetics at proposed § 413.234(f). While we believe using claims data from CYs 2018 and 2019 is appropriate because those years provide us with not only the most complete data set, but also the most accurate data set reflecting paid claims, we are also soliciting comments as to whether we should instead use a single year (CY 2018 or CY 2019) rather than both CYs 2018 and 2019 in our methodology.

(2) Pricing of Calcimimetics – Methodology

For use in the proposed calculation, we would set the price for calcimimetics using values from the most recent calendar quarter of ASP calculations available to the public, at 100 percent of ASP (ASP + 0). The ASP-based value is a CMS-derived weighted average of all of the National Drug Code (NDC) sales prices submitted by drug manufacturers and assigned by CMS to the two existing HCPCS codes for calcimimetics. For each billing code, CMS calculates a weighted average sales price using data submitted by manufacturers, which includes the following: ASP data at the 11-digit NDC level, the number of units of the 11-digit NDC sold and the ASP for those units. Next, the number of billing units in an NDC is determined by the amount of drug in the package. CMS uses the following weighting methodology to determine

the payment limit: (1) Sums the product of the manufacturer's ASP and the number of units of the 11-digit NDC sold for each NDC assigned to the billing and payment code; (2) Divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code, and (3) Weights the ASP for an NDC by the number of billing units sold for that NDC. This calculation methodology is discussed in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69752). The general methodology for determining ASP-based payments for the PFS is authorized in section 1847A of the Act.

ASP-based payment limits published in the quarterly ASP Drug Pricing files include a 6 percent add-on as required in section 1847A of the Act. However, consistent with the TDAPA basis of payment for CY 2020, we use 100 percent of the weighted ASP value, in other words, ASP + 0. In the CY 2020 ESRD PPS final rule, we noted 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. We explained that we believed ASP + 0 is reasonable for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also explained that we believed ASP + 0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56946).

We believe using a value based on the most recent calendar quarter ASP calculations available to the public for both oral and injectable versions of the calcimimetics would provide an accurate representation of the price of calcimimetics for ESRD facilities because it uses

manufacturer sales information that includes discounts (that is, rebates, volume discounts, prompt payment, cash payment specified in section 1847A of the Act). Every calendar quarter, CMS publishes ASP-based payment limits for certain Part B drugs and biological products that are used for payment of such Part B covered drugs and biological products for a specific quarter. The amount that we propose to use for the base rate modifications associated with the oral and injectable versions of the calcimimetics is based on the most recent information on average sales prices net of discounts specified in section 1847A submitted by the manufacturers of each of the drugs.

For this proposed rule, using values from the most recent calendar quarter of ASP calculations available to the public at the time that this rule is being written is the second quarter of 2020¹, and as a result of two-quarter data lag this reflects manufacturer sales data submitted into CMS for the fourth quarter of 2019. For the CY 2021 ESRD PPS final rule, the most recent calendar quarter of ASP calculations available to the public would be the fourth quarter of 2020, which reflects manufacturer sales data submitted into CMS for the second quarter of 2020, and we would use that value for purposes of our final calculation.

We would update these prices by the proposed CY 2021 ESRD PPS base rate update to reflect the estimated costs in CY 2021. That is, we would first add the calculated per treatment payment amount to the ESRD PPS base rate to include calcimimetics, and then we would apply the annual payment rate update. The proposed calculation for the addition to the ESRD PPS base rate is discussed in the following section.

Therefore, we propose to add § 413.234(f) that CMS would use 100 percent of the values

¹ <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files>, April 2020 ASP Pricing File

from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic to calculate a price for each form of the drug. We solicit comments on the proposed use of the values from the most recent calendar quarter ASP + 0 calculations available to the public for calcimimetics for setting the price and the proposed language at § 413.234(f).

(3) Calculation of the Addition to the ESRD PPS Base Rate to Include Calcimimetics

To calculate the proposed amount for calcimimetics that would be added to the ESRD PPS base rate, we applied the values from the most recent calendar quarter 2020 ASP + 0 calculations available to the public for calcimimetics to CYs 2018 and 2019 calcimimetic utilization data to calculate the calcimimetic expenditure amount for both years. As stated in section II.B.1.c.(1) of this proposed rule, one unit of J0604 (oral calcimimetic, cinacalcet) is 1 mg and one unit of J0606 (injectable calcimimetic etelcalcetide) is 0.1 mg. That is, we determined that 1,824,370,957 total units (mg) of oral calcimimetics were used in CYs 2018 and 2019. With regard to injectable calcimimetics, we determined that 306,714,207 total units (0.1 mg) were used in CYs 2018 and 2019. This use indicates that 33.9 percent of ESRD beneficiaries received calcimimetics in CYs 2018 and 2019. For this proposed rule, we used the values from the most recent calendar quarter ASP + 0 calculations available to the public, which is the second quarter of 2020. This information can be found on the ESRD Payment website: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug>. We used \$0.231 per mg for the oral calcimimetic and \$2.20 per 0.1 mg for the injectable calcimimetic. The prices per unit correspond to 1 mg and 0.1 mg for cinacalcet and etelcalcetide respectively. (We note that, for the CY 2021 ESRD PPS final rule, we would update the ASP + 0 based value on the most recent calendar quarter calculations available to the

public.) Multiplying the utilization of the oral and injectable calcimimetics by their respective ASP and then adding the expenditure amount for both forms of calcimimetics together would be the total 2-year (CYs 2018 and 2019) calculated calcimimetic expenditure amount. That is, for this proposed rule, we calculated the total calcimimetic expenditure amount of \$1,096,200,947. The total number of paid hemodialysis-equivalent dialysis treatments furnished to Medicare ESRD beneficiaries in CYs 2018 and 2019 was 90,014,098. This total number of paid treatments reflects all paid dialysis treatments regardless of whether a calcimimetic was furnished. Dividing the calcimimetic expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments provides an average per treatment payment amount of \$12.18.

We then reduced this amount by 1 percent to account for the outlier policy under § 413.237 to get a total of \$12.06 ($\$12.18 \times .99 = \12.06). Under our proposal, we would apply this 1 percent reduction before increasing the base rate to account for outlier payments that would be paid beginning January 1, 2021 for calcimimetics since they would become ESRD outlier services eligible for outlier payments under § 413.237. As we discussed in section II.B.1.c of this proposed rule, in developing the proposed methodology for including calcimimetics in the ESRD PPS base rate, we considered the methodology applied when we developed the ESRD PPS base rate. In the CY 2011 ESRD PPS final rule (75 FR 49074 through 49075), we explained the budget neutrality adjustments applied to the unadjusted ESRD PPS base rate to account for statutorily mandated reductions. Because we are proposing to modify the ESRD PPS base rate to include calcimimetics, which beginning January 1, 2021 would become ESRD outlier services, we focused on the outlier adjustment. That is, in CY 2011 we applied a 1 percent reduction to the unadjusted ESRD PPS base rate to account for outlier

payments. In order for the application of the 1 percent outlier to be maintained, we believe the 1 percent must be excluded from the addition to the ESRD PPS base rate for calcimimetics.

Then, to determine the estimated costs in CY 2021 we would inflate the average per treatment payment amount for calcimimetics (\$12.06) to 2021 using the CY 2021 ESRD PPS base rate update. As discussed in section II.B.4.d of this proposed rule, the proposed CY 2021 ESRD PPS base rate is \$255.59. This amount reflects a proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed base rate addition of \$12.06 to include calcimimetics, and the proposed CY 2021 ESRD PPS payment rate update of 1.8 percent. We believe that using the annual payment rate update effectively updates the prices set for calcimimetics from CY 2020 to CY 2021 because this is consistent with how the other components of the base rate are updated for inflation each year, which includes drugs. We note, that the inflation factor used for drugs and biological products for the ESRD bundled market basket is the Producer Price Index as discussed in the CY 2019 ESRD PPS final rule (83 FR 56958 through 56959).

Therefore, we propose to add § 413.234(f) that CMS would multiply the utilization of the oral and injectable calcimimetics by their respective prices and add the expenditure amount for both forms together to calculate the total calcimimetic expenditure amount. Then, CMS would divide the total calcimimetic expenditure amount by the total number of paid hemodialysis-equivalent dialysis treatments in CYs 2018 and 2019, to calculate the average per-treatment payment amount. CMS would reduce the average per-treatment payment amount by 1 percent to account for the outlier policy under § 413.237 in order to determine the amount added to the ESRD PPS base rate.

In keeping with the principles of a PPS, which include motivating healthcare providers to

structure cost-effective, efficient patient care that avoids unnecessary services, thereby reining in costs, we believe the cost of the calcimimetics should be spread across all the dialysis treatments, rather than be directed only to the patients receiving the calcimimetics.

We solicit comments on the proposed revisions to § 413.234 to add paragraph (f) to § 413.234 to establish the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment.

As an alternative methodology, we considered dividing the total Medicare expenditures for all calcimimetics in CYs 2018 and 2019 (approximately \$2.3 billion) by the total number of paid hemodialysis-equivalent dialysis treatments furnished during that same time period. However, this approach would not factor in the impact of oral generic calcimimetics, which entered the market from late December 2018 through early January 2019. For example, under the proposed methodology, the ASP calculations incorporate the more recent pricing of the oral generic calcimimetics into the weighting which has resulted in a significant decline in the ASP-based value. In addition, this alternative methodology would not reflect our current policy to base the TDAPA on ASP + 0, since in CYs 2018 and 2019 we paid for calcimimetics using the TDAPA at ASP + 6. We believe it is more appropriate for the ESRD PPS base rate to reflect the values from the most recent calendar quarter of ASP calculations available since that aligns with how ESRD facilities would be purchasing and furnishing the oral calcimimetics rather than using expenditure data from previous periods. We believe that ESRD facilities would want to support CMS's goal of lower drug and biological products prices for its beneficiaries. In addition, this alternative methodology would have a more significant impact on beneficiary cost sharing in terms of a higher 20 percent co-pay than the proposed methodology in this proposed rule. We solicit comment on this alternative methodology, which would entail dividing the total Medicare

expenditures (that is, actual spend) for all calcimimetics in CYs 2018 and 2019 by the total number of paid hemodialysis-equivalent dialysis treatments furnished during that same time period.

2. Proposed Changes to the TPNIES Eligibility Criteria

a. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established a transitional add-on payment adjustment for certain 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, in order to support ESRD facility use and beneficiary access to these new technologies. We established this payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies, which we call the TPNIES.

We established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, CMS will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) has a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year, (5) is innovative, meaning it meets the criteria

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

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that CMS will use the following criteria to evaluate substantial clinical improvement (SCI) for purposes of the TPNIES under the ESRD PPS, based on the inpatient hospital prospective payment system (IPPS) SCI criteria in § 412.87(b)(1) and related guidance: Section 412.87(b)(1) includes the criteria used under the IPPS new technology add-on payment (NTAP) to determine whether a new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, and most importantly, the totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than

allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or

- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; (6) an improved quality of life; or (7) a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

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

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

We also established a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87(b)(1). Specifically, similar to the IPPS NTAP, we wanted to align our goals with the agency's efforts to transform the healthcare delivery system for the ESRD beneficiary through competition and innovation to provide patients with better value and results. We believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payments similar to the IPPS NTAP program and to provide innovators with standard criteria for both inpatient and outpatient settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we will announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. The TPNIES applications for CY 2021 are discussed in section II.C. of this proposed rule. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the payment adjustment would take effect, and FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We stated in the

CY 2020 ESRD PPS final rule (80 FR 60690) that we would establish a workgroup of CMS medical and other staff to review the studies and papers submitted as part of the TPNIES application, the public comments we receive, and the FDA marketing authorization and HCPCS application information and assess the extent to which the product provides SCI over current technologies.

We established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. Section 413.236(d)(1) states that the TPNIES is paid for 2-calendar years. Section 413.236(d)(2) provides that, following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Under § 413.236(e)(1), the Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for the new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in § 413.236(b) using verifiable information from the following sources of information, if available: (1) the invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

b. Proposed Changes to Eligibility for the TPNIES

Currently, in § 413.236(b)(2), one eligibility requirement for the TPNIES is that an equipment or supply must be new, meaning it is granted marketing authorization by FDA on or after January 1, 2020. In establishing this requirement, we tied what is considered new to

January 1, 2020, the effective date of the TPNIES policy. We explained in the CY 2020 ESRD PPS final rule (84 FR 60685) that by including FDA marketing authorizations on or after January 1, 2020, we intended to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. While we continue to believe it is appropriate to tie the newness requirement to the date of the FDA marketing authorization for the reasons discussed in the CY 2020 ESRD PPS final rule, we do not believe newness should be tied to the effective date of the TPNIES policy going forward, for the reasons discussed below. In addition, we believe this eligibility criterion should address when an equipment or supply is no longer considered new. Under the current requirement at § 413.236(b)(2), we could receive an application for the TPNIES for equipment and supplies many years after FDA marketing authorization, when the equipment is no longer new.

In the CY 2020 ESRD PPS proposed rule (84 FR 38353), while we proposed to define new renal dialysis equipment and supplies as those that are granted marketing authorization by FDA on or after January 1, 2020, we also solicited comment on whether a different FDA marketing authorization date, for example, on or after January 1, 2019, might be appropriate. We explained in the CY 2020 ESRD PPS final rule (84 FR 60688 through 60689) that while some commenters expressed support for the proposed definition, most of the comments were focused on the merits of establishing a date for newness that precedes the effective date of the TPNIES policy and whether all renal dialysis equipment and supplies must seek FDA marketing authorization. None of the comments addressed whether tying TPNIES eligibility to the TPNIES policy effective date or any fixed date would limit the TPNIES to new and innovative equipment and supplies.

After careful consideration of these comments, we decided to finalize the proposed

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

After further consideration, we no longer believe an item should be considered new based on the TPNIES policy effective date of January 1, 2020. Rather, we believe that it is important for the TPNIES policy to provide a window of time when a new renal dialysis equipment or supply is considered new to provide transparency to potential applicants. We note that, under this proposal, the TPNIES policy would still be effective as of January 1, 2020 and therefore no equipment or supply receiving FDA marketing authorization before January 1, 2020 would be eligible for the TPNIES. However, we are proposing to revise § 413.236(b)(2) to remove “on or after January 1, 2020” and to reflect the definition of new to mean, within 3 years beginning on

the date of FDA marketing authorization. By defining new in this manner, we would be giving entities wishing to apply for the TPNIES for their equipment or supply 3 years beginning on the date of FDA marketing authorization in which to submit their applications, while still limiting eligibility for the TPNIES to new technologies. We are proposing a 3-year newness window to be consistent with the timeframes under the IPPS NTAP requirements in § 412.87(b)(2). Under the NTAP, new technologies are considered to be new for 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. We note, under the hospital outpatient PPS, the pass-through payment application for a medical device must also be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.

In addition, we propose to revise § 413.236(b) to remove “For dates of service occurring on or after January 1, 2020” and to revise § 413.236(a) to reflect the January 1, 2020 effective date of the TPNIES policy finalized in the CY 2020 ESRD PPS final rule. We also are proposing other revisions to this paragraph, which are discussed in section II.B.3.b.(1) of this proposed rule.

We are seeking comment on our proposal to define new for purposes of the TPNIES eligibility as within 3 years beginning on the date of FDA marketing authorization. In addition, it is our understanding that there may be situations in which a manufacturer has FDA marketing authorization for an item, but the process of manufacturing the item has been delayed, for example, by a Public Health Emergency (PHE), such as the current COVID-19 pandemic.

Therefore, we are also seeking comment on the number of years for an item to be considered new, or if newness should be based on different criteria such as the later of marketing availability or the date of FDA marketing authorization.

Currently, § 413.236(b)(4) requires applicants for the TPNIES to have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year. Section 413.236(c) currently requires applicants for TPNIES to have the FDA marketing authorization for the equipment or supply by September 1 prior to the particular calendar year.

After publication of the CY 2020 ESRD PPS final rule, CMS updated its HCPCS Level II coding procedures to enable shorter and more frequent HCPCS code application cycles. Beginning in January 2020, CMS implemented quarterly HCPCS code application opportunities for drugs and biological products, and biannual application opportunities for DMEPOS and other non-drug, non-biological items and services.

As the Administrator of CMS announced² in May 2019, this change is part of CMS' broader, comprehensive initiative to foster innovation and expedite adoption of and patient access to new medical technologies. CMS' delivery on this important goal necessitated procedural changes that balance the need to code more frequently with the amount of time necessary to accurately process applications. CMS has released two documents with detailed information on the updated HCPCS Level II coding procedures, application instructions, and deadlines for 2020. Both documents, Healthcare Common Procedure Coding System (HCPCS)

² <https://www.cms.gov/newsroom/press-releases/cms-outlines-comprehensive-strategy-foster-innovation-transformative-medical-technologies>

Level II Coding Procedures³, and Healthcare Common Procedure Coding System (HCPCS) Level II Code Modification Application Instructions for the 2020 Coding Cycle⁴ are available on the CMS website. Under the new guidance, coding cycles for DMEPOS items and services will occur no less frequently than biannually. For 2020, the deadline for HCPCS Level II code applications for biannual Coding Cycle 1 for DMEPOS items and services was January 6, 2020 with issuance of final code decisions occurring July 2020. These final code decisions are effective October 1, 2020. For biannual Coding Cycle 2, the code application deadline for DMEPOS items and services is June 29, 2020 with issuance of final code decisions occurring January 2021 or earlier. These final code decisions are effective April 1, 2021. These dates are specific for 2020 and may change annually. Specific dates for biannual Coding Cycles 1 and 2 for future years will be published on the HCPCS website annually.

Under the new biannual Coding Cycle 2 for DMEPOS items and services, in order to obtain a final HCPCS Level II code decision by January 1, 2021, the applicant must submit a complete HCPCS Level II code application along with the FDA marketing authorization documentation to CMS by June 29, 2020. In light of the change to biannual coding cycles, we have reassessed the TPNIES eligibility criterion in § 413.236(b)(4), which is related to submission of the HCPCS Level II code application as well as § 413.236(c), which discusses the deadlines for consideration of new renal dialysis equipment or supply applications and have found that they conflict with the current HCPCS Level II coding guidelines.

Because our HCPCS Level II coding guidelines require that applicants submit complete

³ <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf>

⁴ <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2020-HCPCS-Application-and-Instructions.pdf>

code applications for DMEPOS items and services to CMS by the deadline for biannual Coding Cycle 2 as specified in the HCPCS Level II coding guidance on the CMS website in order for a final HCPCS Level II code decision to be made by the following January 1 and require that documentation of FDA marketing authorization be submitted by the applicant to CMS by the HCPCS Level II code application deadline, we propose to align the TPNIES regulation at § 413.236(b)(4) and (c) with these guidelines. We believe this alignment would provide consistency across CMS processes and transparency on deadlines for applicants for the TPNIES. In the event of a delay in the final HCPCS Level II coding decision, a miscellaneous code will be used in the interim until a final coding decision is made.

We are also proposing to correct a technical error in § 413.236(b)(4), which requires the HCPCS application to be submitted by September 1 “of” the particular calendar year, meaning the year in which the payment adjustment would take effect. In accordance with the TPNIES policy, we would need to have the HCPCS application submitted “prior to” the particular calendar year to be able to make a determination of TPNIES eligibility for payment to occur in the particular calendar year.

Therefore, we propose to revise at § 413.236(b)(4) to add the word “complete” and to replace “September 1” with “the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website,” and replace the word “of” with “prior to” to reflect that the HCPCS code application for biannual Coding Cycle 2 must be complete and submitted as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. This HCPCS application submission deadline for a HCPCS Level II code application may result in a final HCPCS code determination by January 1, when the TPNIES payment would begin. We

note that, for 2020 biannual Coding Cycle 2, final decisions on HCPCS Level II codes issued by January 1, 2021 are not effective until April 1, 2021. For this reason, during this interim period, we propose to use a miscellaneous HCPCS code to provide the TPNIES payment. In the event of a delay in the final HCPCS Level II coding decision, a miscellaneous code will be used in the interim until the later effective date. In addition, we propose a technical change to § 413.236(b)(4) to be consistent with how CMS references the HCPCS Level II coding procedures. That is, we propose to revise § 413.236(b)(4) from “official Level II HCPCS coding procedures” to “HCPCS Level II coding procedures on the CMS website”.

In addition, we propose to revise § 413.236(c) to replace “September 1” with “the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website” to reflect that FDA marketing authorization for the new and innovative equipment or supply must accompany the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year. Although applicants for TPNIES may submit a TPNIES application while the equipment or supply is undergoing the FDA marketing authorization process (since the deadline for the TPNIES application is February 1), under our proposal, FDA marketing authorization of the equipment or supply must be granted prior to the HCPCS Level II code application deadline. If FDA marketing authorization is not granted prior to the HCPCS Level II code application deadline, the TPNIES application would be denied and the applicant would need to reapply and submit an updated application by February 1 of the following year or within 3 years beginning on the date of FDA marketing authorization, in accordance with the proposed revisions to § 413.236(b)(2) discussed previously in this proposed rule.

Currently, § 413.236(b)(5) requires that the new equipment or supply be innovative,

meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance. As discussed previously in this proposed rule, § 412.87(b)(1) includes the criteria used under the IPPS NTAP to determine whether a new technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In § 413.236(b)(5) we adopt the same SCI criteria to determine if a new renal dialysis equipment or supply is innovative for purposes of the TPNIES under the ESRD PPS. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690) our intention to adopt any future modifications to the IPPS SCI criteria so that innovators would have standard criteria to meet for both settings. While we adopted the IPPS SCI criteria under § 412.87(b)(1), we did not adopt the alternative pathway for breakthrough devices (84 FR 42296) under the ESRD PPS.

In the fiscal year (FY) 2020 IPPS final rule (84 FR 42180 through 42181), CMS codified additional SCI criteria that had been included in manuals and other sub-regulatory guidance. In accordance with the reference to § 412.87(b)(1), we adopted the FY 2020 IPPS changes to the SCI criteria, and any future changes to the SCI criteria, by reference, unless and until we make any changes to the criteria through notice-and-comment rulemaking. Although the codification of the related guidance for the IPPS SCI occurred prior to the publication of the CY 2020 ESRD PPS final rule, we inadvertently included a reference to related guidance in § 413.236(b)(5). Therefore, we propose to revise § 413.236(b)(5) to remove “and related guidance” to reflect that all related SCI guidance has now been incorporated into § 412.87(b)(1).

3. Proposed Expansion of the TPNIES for New and Innovative Capital-Related Assets that are Home Dialysis Machines When Used in the Home for a Single Patient

a. Background

In response to the proposed expansion of the TDAPA in the CY 2019 ESRD PPS

proposed rule, 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.

Other commenters, including a professional association and a large dialysis organization (LDO) 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). 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 because we did not include any proposals regarding this issue in the CY 2019 ESRD PPS proposed rule, we considered these suggestions to be beyond the scope of that rule.

However, in response to this feedback, in the CY 2020 ESRD PPS proposed rule (84 FR 38354 through 38355), we agreed that additional payment for certain renal dialysis equipment and supplies may be warranted under specific circumstances. We proposed to provide the TPNIES for certain new and innovative renal dialysis equipment and supplies furnished by ESRD facilities, but exclude from eligibility capital-related assets, which are defined in the Provider Reimbursement Manual (Pub. Law 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/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>. Examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems.

As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38354), we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and they are generally used for multiple patients. In addition, we noted that since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. For these reasons, we therefore believed capital-related assets should be excluded from eligibility for the TPNIES at that time, and we proposed an exclusion to the eligibility criteria in § 413.236(b)(6). However, we noted that CMS uses capital-related asset cost data from cost reports 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.

In response to the proposed exclusion of capital-related assets, we received comments from a device manufacturers' association, which stated that since most medical equipment is purchased as a capital-related asset, the TPNIES effectively would exclude the innovative equipment identified in the title of the adjustment. The association asserted that meaningful clinical improvements and patient experience improvements are arguably more likely to come from innovation outside single-use supplies. The association maintained that expanding the TPNIES to include medical equipment, regardless of how it is purchased by the provider, would stimulate greater investment in a broader array of new technologies for ESRD patients.

In response, we stated in the CY 2020 ESRD PPS final rule (84 FR 60688) that we

recognize that accounting for renal dialysis service equipment can vary depending on the individual ESRD facility's business model. For example, when the owner of the capital-related asset retains title, then the renal dialysis service equipment is a depreciable asset and depreciation expense could be itemized. When there is no ownership of the renal dialysis service equipment, then the item is recorded as an operating expense.

In addition, in response to comments regarding capital leases, we noted that regulations at § 413.130(b)(1) specify that leases and rentals are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. We stated that in the future, we will be closely examining the treatment of capital-related assets under Medicare, including our regulations at § 412.302 regarding capital costs in inpatient hospitals and § 413.130, as they relate to accounting for capital-related assets, including capital leases and the newly implemented guidance for finance lease arrangements, to determine if similar policies would be appropriate under the ESRD PPS.

b. Proposed Additional Payment for New and Innovative Capital-related Assets that are Home Dialysis Machines When Used in the Home for a Single Patient

Following publication of the CY 2020 ESRD PPS final rule, in which we finalized the TPNIES policy, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we received additional comments and information from dialysis equipment and supply manufacturers, and a Technical Expert Panel (TEP) meeting held in December 2019, regarding the need for additional payment for capital-related assets under the ESRD PPS.

We also took into account the President's Executive Order, signed on July 10, 2019,

aimed at transforming kidney care in America. The Executive Order discussed many new 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. Currently, most dialysis is furnished at ESRD facilities. In-center dialysis can be time-consuming and burdensome for patients. In addition, the current system prioritizes payment to in-center dialysis and the goal of the agency is to incentivize in-home dialysis. A key focus of the Executive Order is the effort to encourage in-home dialysis.

The Executive Order is available at: <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>.

In conjunction with the Executive Order, HHS laid out three goals for improving kidney health (see <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>):

- Reducing the number of Americans developing ESRD by 25 percent by 2030.
- Having 80 percent of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant; and
- Doubling the number of kidneys available for transplant by 2030.

In addition, in connection with the President's Executive Order, on July 10, 2019, CMS issued a proposed rule (84 FR 34478) to implement a new mandatory payment model, known as the ESRD Treatment Choices (ETC) Model, which would provide new incentives to encourage the provision of dialysis in the home. The proposed ETC Model would be a mandatory payment

model, focused on encouraging greater use of home dialysis and kidney transplants for ESRD beneficiaries among ESRD facilities and Managing Clinicians located in selected geographic areas.

Lastly, we note that ESRD patients who receive in-center dialysis are particularly vulnerable during a PHE and other disasters, and that greater use of home dialysis modalities may expose these patients to less risk. The U.S. is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 190 countries internationally, and all 50 States and the District of Columbia. The virus has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2) and the disease it causes has been named “coronavirus disease 2019” (‘COVID-19’).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of international concern.” On January 31, 2020, the Secretary determined that a PHE exists for the U.S. to aid the nation’s healthcare community in responding to COVID-19 and on April 21, 2020, the Secretary renewed, effective April 26, 2020, the determination that a PHE exists. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President of the U.S. declared the COVID-19 pandemic a national emergency.

The experience of multiple countries across the globe has demonstrated that older patients and patients with multiple comorbidities and underlying health conditions are patients who are more susceptible to the virus and have a higher risk of morbidity than younger patients without underlying health conditions. Per the CDC, the risk factors for COVID-19 include older adults and people of any age who have serious underlying medical conditions, such as diabetes

and chronic kidney disease undergoing dialysis. Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID-19. Therefore, it is important to reduce the risk of infection and this can be done through isolating patients from in-center exposure by encouraging home dialysis.

Home dialysis would mitigate the risks associated with dialysis for these patients if the pandemic lasts longer than expected or is refractory in some way.

(1) Proposed Expansion of the TPNIES to Certain New and Innovative Capital-Related Assets that are Home Dialysis Machines When Used in the Home for a Single Patient

In response to the President's Executive Order, the various HHS home dialysis initiatives, and the particular benefits of home dialysis for ESRD beneficiaries during PHEs like the current COVID-19 pandemic, which we discussed in the previous section, and in consideration of the feedback we have received from stakeholders, we agree that additional payment through the TPNIES for certain capital-related assets may be warranted under specific circumstances outlined in this section of the proposed rule. We note that in the CY 2020 ESRD PPS final rule (84 FR 60607), we specifically excluded capital-related assets from the TPNIES. In commenting on the proposed rule, most stakeholders expressed concern that the TPNIES would exclude capital-related assets. In our response to commenters, we acknowledged that significant innovation and technology improvement is occurring with dialysis machines and peritoneal dialysis cyclers, as well as innovation in the efficiency and effectiveness of water systems. However, at that time we did not have enough information regarding current usage of the various financial and leasing arrangements, such as those involving capital leases for depreciable assets versus operating leases recorded as operating expenses. In addition, we noted that we would need to assess methodological issues regarding depreciation to determine whether TPNIES

eligibility for these items would be appropriate.

We stated in the CY 2020 ESRD PPS final rule that we needed to further study the specifics of the various business arrangements for equipment related to renal dialysis services. This would include items that are: (1) Purchased in their entirety and owned as capital-related assets; (2) assets that are acquired through a capital lease arrangement; (3) equipment obtained through a finance lease and recorded as an asset per the Financial Accounting Standards Board (FASB) guidance on leases (Topic 842) effective for fiscal years beginning after December 15, 2018;⁵ or (4) equipment obtained through an operating lease and recorded as an operating expense. In addition to the variety of business arrangements, we noted, there are unknown issues relating to ownership of the item and who retains title, which may affect the equipment's maintenance expenses for capital-related assets.

Further, there is the issue of single use versus multiple use for capital-related assets used for renal dialysis services. For example, some capital-related assets used in-center and in the home setting, such as skilled nursing facilities (SNFs) and nursing facilities, may be used by multiple patients in a day, and by multiple patients over their useful lifetime. Specifically, equipment classified as capital-related assets may be refurbished and used by another patient. For example, capital-related assets used by multiple patients in a day could be Hoyer lifts to transfer patients and wheelchair scales. In this proposed rule, we are not proposing to include capital-related assets with multi-patient usage as being eligible for the TPNIES because we are supporting the President's Executive Order and HHS goals of promoting home dialysis, which involves a single machine for patient use. In addition, as we discussed earlier in this section, it is more complicated to develop a per treatment payment amount for those items. However, we

⁵ https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=1176167901010&acceptedDisclaimer=true

seek comments on this aspect of our proposal, and we intend to gather additional information about how ESRD facilities obtain their capital-related assets that have multi-patient usage in future meetings with the TEP.

As we further studied this issue, we determined that one business arrangement, that is, where the capital-related assets are purchased in their entirety and owned as capital-related assets, could be considered for TPNIES eligibility. We continue to analyze other business arrangements, but we understand that this arrangement is more straightforward due to ownership being clear, retained at the end of the TPNIES period, and on the facility's balance sheet. CMS' intent would be to pay for assets that are owned, whether purchased or attained through a capital lease. The entity who holds the title to the asset is the legal owner. At the end of the TPNIES period, the entity retains ownership of the asset. We would not pay TPNIES for equipment that is leased, as the ESRD facility has no ownership rights. We believe this is an appropriate initial step to support home dialysis.

In support of the HHS goals and initiatives to increase home dialysis following the President's Executive Order, we propose to provide the TPNIES for eligible new and innovative capital-related assets that are home dialysis machines when used in the home. We would limit the payment for new and innovative dialysis machines to those used for home dialysis in order to target the additional payment through the TPNIES to equipment that supports the various home dialysis initiatives currently underway, as discussed previously in this section of the proposed rule. As more ESRD patients and their nephrologists and other clinicians opt for home dialysis modalities, we would seek to support ESRD facility use and beneficiary access to the latest technological improvements to hemodialysis and peritoneal dialysis home dialysis machines. As we explained in prior ESRD PPS rules establishing the TDAPA and TPNIES, ESRD facilities

face unique challenges in incorporating new renal dialysis drugs, biological products, equipment and supplies into their businesses and these add-on payment adjustments are intended to support ESRD facilities' use of new technologies during the uptake period for these new products.

To codify our proposals for expanding the TPNIES to include capital-related assets that are home dialysis machines when used in the home for a single patient, we are proposing further revisions to § 413.236, in addition to the revisions proposed earlier in section II.B.2 of this proposed rule.

Specifically, we propose to revise the heading at § 413.236(a) and adding paragraphs (a)(1) and (2) to distinguish this paragraph as both the “basis and definitions.” We propose to define “capital-related asset” at § 413.236(a)(2) as an asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets. This proposed definition is based on the definition of “depreciable assets” in the Provider Reimbursement Manual (chapter 1, section 104.1). The Provider Reimbursement Manual is available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>.

We propose to define “home dialysis machines” at § 413.236(a)(2) as hemodialysis machines and peritoneal dialysis cyclers in their entirety, meaning that one new part of a machine does not make the entire capital-related asset new, that receive FDA marketing authorization for home use and when used in the home for a single patient. FDA provides a separate marketing authorization for equipment intended for home use, and this proposal is focused on supporting efforts to increase home dialysis.

We propose to define “particular calendar year” at § 413.236(a)(2) as the year in which the payment adjustment specified in paragraph (d) of § 413.236 would take effect. We also propose to include definitions for the terms “depreciation,” “straight-line depreciation method,” and “useful life,” which are discussed in section II.B.3.b.(2) of this proposed rule.

We propose to revise § 413.236(b)(6) to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in the proposed revisions to § 413.236(b). We also propose to remove “that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired)” in § 413.236(b)(6) since we are proposing a separate definition for “capital-related asset” at § 413.236(a)(2).

Under this proposal, we would continue to exclude other capital-related assets from the TPNIES that are not home dialysis machines when used in the home because those items would not be advancing HHS’s goal of increasing home dialysis. Examples of capital-related assets that would continue to be excluded from TPNIES are water purification systems and dialysis machines when they are used in-center. We continue to believe that we should not provide additional payment for these capital-related assets because the cost of these items are captured in cost reports and reported in the aggregate, depreciate over time, are generally used for multiple patients and, most importantly, it would not support the goal of increasing use of home dialysis. However, capital-related assets that are home dialysis machines when used in the home are intended for use by a single patient and can be reported on a per treatment basis on the ESRD facility’s claim. These characteristics provide for a simple methodology for aligning the use of the asset with the per treatment TPNIES payment.

As we stated previously in this section, we are not proposing to expand the TPNIES eligibility to in-center dialysis machines or home dialysis machines when they are used in-center. Currently, our focus is promoting the increase in home dialysis rather than in-center dialysis. In addition, in-center dialysis machines are used by multiple patients each day and would require additional analysis, along with 72X claims and cost report modifications, in order to provide payment. For this same reason, we are not proposing to provide the TPNIES for home dialysis machines when they are used in SNFs and nursing facilities and are used by multiple patients each day.

We believe the SCI criteria required under § 413.236(b)(5), with our proposed revisions, and the process used to evaluate SCI currently applicable to TPNIES equipment and supplies are also appropriate for identifying new and innovative capital-related assets that are home dialysis machines that are worthy of temporary additional payment under the ESRD PPS. This approach would provide consistent criteria and evaluation for all equipment and supplies that are potentially eligible for the TPNIES. In addition, we want to ensure that we do not pay the TPNIES for new home dialysis machines that are substantially similar to existing machines and not truly innovative.

Under our proposal, we would utilize the determination process we established last year for the TPNIES and those requirements we are proposing to revise in section II.B.2 of this proposed rule. That is, pursuant to § 413.236(c), interested parties would submit all information necessary for determining that the home dialysis machine meets the TPNIES eligibility criteria listed in § 413.236(b). This 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 note, for purposes of determining whether the home dialysis machine is new under § 413.236(b)(2), we would look at the date the machine is granted marketing authorization by FDA for home use.

Using our current process at § 413.236(c), we would provide a description of the new home dialysis machine and pertinent facts in the ESRD PPS proposed rule so the public may comment on them and then publish the results in the ESRD PPS final rule. We would consider whether the new home dialysis machine meets the eligibility criteria specified in the proposed revisions to § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. Per § 413.236(c), we would only consider, for additional payment using the TPNIES for a particular calendar year, an application for a capital-related asset that is a home dialysis machine we receive by February 1 prior to the particular calendar year. If the application is not received by February 1, the application would be denied and the applicant would need to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with the proposed revisions to § 413.236(b)(2). We note, applicants are expected to submit information on the price of their home dialysis machine as part of the TPNIES application. While we recognize this information is proprietary, CMS requests this information along with the equipment or supply's projected utilization.

For example, under our proposed revisions to § 413.236, in order for a particular home dialysis machine to be eligible for the TPNIES under the ESRD PPS beginning in CY 2022, CMS must receive a complete application meeting our requirements no later than

February 1, 2021. FDA marketing authorization and submission of the HCPCS Level II code application for Coding Cycle 2 for DMEPOS items and services must occur as specified in the HCPCS Level II coding guidance on the CMS website. We would include a discussion of the new capital-related asset that is a home dialysis machine in the CY 2022 ESRD PPS proposed rule and the CMS final determination would be announced in the CY 2022 ESRD PPS final rule. If the home dialysis machine qualifies for the TPNIES, the payment adjustment would begin January 1, 2022 with a miscellaneous code and the designated HCPCS code would be effective April 1, 2022.

(2) Pricing of New and Innovative Capital-Related Assets that are Home Dialysis Machines When Used in the Home

As we explained in the CY 2020 ESRD PPS final rule (84 FR 60692), we are not aware of pricing compendia currently available to price renal dialysis equipment and supplies for the TPNIES. We also noted that, unlike new renal dialysis drugs and biological products eligible for the TDAPA, ASP and WAC pricing do not exist for renal dialysis equipment and supplies, including capital-related assets that are home dialysis machines.

In addition, as we explained in the CY 2020 ESRD PPS final rule (84 FR 60692), ESRD facility charges are gross values; that is, charges before the application of allowances and discounts deductions. We believe the TPNIES payment amount should reflect the discounts, rebates and other allowances the ESRD facility (or its parent company) receives. These terms are defined in the Provider Reimbursement Manual (chapter 8).⁶ If the TPNIES payment amount does not reflect discounts, rebates and other allowances, the price would likely exceed the

⁶ Medicare Provider Reimbursement Manual (chapter 8). Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R450PR1.pdf>.

facility's cost for the item and result in higher co-insurance obligations for beneficiaries.

For this reason, in § 413.236(e), we established an invoice-based approach for MACs to use on behalf of CMS to price new and innovative renal dialysis equipment and supplies that meet the eligibility criteria for the TPNIES. We require the MACs to establish a price, using verifiable information from the following sources of information, if available: (1) the invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60692 through 60693), in order to maintain consistency with the IPPS NTAP payment policy and to mitigate the Medicare expenditures incurred as a result of the TPNIES, we finalized a policy at § 413.236(d) to base the TPNIES payment on 65 percent of the MAC-determined price.

We believe that the invoice-based approach established for the TPNIES also should be applied to capital-related assets that are home dialysis machines, which are the focus of this proposal. However, capital-related assets that are home dialysis machines when used in the home for a single patient are depreciable assets as defined in the Provider Reimbursement Manual (chapter 1, section 104), which defines depreciation as “that amount which represents a portion of the depreciable asset's cost or other basis which is allocable to a period of operation.” The Provider Reimbursement Manual provides the American Institute of Certified Public Accountant's definition of depreciation as a process of cost allocation: "Depreciation accounting is a system of accounting which aims to distribute the cost or other basic value of tangible capital

assets, less salvage (if any), over the estimated useful life of the unit (which may be a group of assets) in a systematic and rational manner. It is a process of allocation, not of valuation.

Depreciation for the year is the portion of the total charge under such a system that is allocated to the year."

Because capital-related assets that are home dialysis machines when used in the home for a single patient are depreciable assets, we are proposing to apply a 5-year straight-line depreciation method to determine the basis of the TPNIES for these items. The Provider Reimbursement Manual, (chapter 1, section 116.1) discusses the straight-line depreciation method as a method where the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life. Section 104.17 of the Provider Reimbursement Manual discusses that the useful life of a capital-related asset is its expected useful life to the provider, not necessarily the inherent useful or physical life. Further, the manual provides that under the Medicare program, only the American Hospital Association (AHA) guidelines may be used in selecting a proper useful life for computing depreciation.

Using the Provider Reimbursement Manual definitions as the basis, we propose to define the following terms at § 413.236(a)(2): "depreciation" as the amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation; "straight-line depreciation method" as a method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life; and "useful life" as the estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

In keeping with the Medicare policy, we propose to rely on the AHA guidelines to determine the useful life of a capital-related asset that is a home dialysis machine. That is, the

useful life of a home dialysis machine is 5 years. Since we are proposing a methodology using the Provider Reimbursement Manual's guidance, we believe these terms are appropriate to codify for purposes of calculating the price of a home dialysis machine that is a capital-related asset.

That is, under § 413.236(e), MACs, on behalf of CMS, would establish prices, using verifiable information as described above, for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility criteria specified in § 413.236(b). This price would be the only element used to determine the total cost basis for applying the straight-line depreciation method. For example, we would exclude financing, sales tax, freight, installation and testing, excise taxes, legal or accounting fees, and maintenance. This specific price element would act as the proxy for the all-encompassing cost basis in other accounting methodologies. Using the straight-line depreciation method, we would divide the MAC-determined price by the useful life of the capital-related asset that is a home dialysis machine when used in the home for a single patient. The resulting number is the annual allowance.

We considered other depreciation methods, such as units of production and accelerated depreciation methods such as double declining balance and sum-of-the-years-digits, but concluded that these methods would be more complex to implement and that the simpler method would be preferable for the calculation of an add-on payment adjustment. In addition, since we are not reimbursing the cost of the equipment, nor are we revising the ESRD PPS at the end of the two-year add-on payment period, based on the information gathered, we believe this policy is appropriate for encouraging and supporting the uptake of new and innovative renal dialysis equipment and supplies.

In order to determine the basis of payment for capital-related assets that are home dialysis machines when used in the home for a single patient, we are proposing certain additional steps that MACs would take after determining the price to develop the TPNIES per treatment payment amount. That is, we propose to add paragraph (f) to § 413.236 to establish the pricing for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility criteria in § 413.236(b). We are proposing in § 413.236(f)(1) that, using the price determined under § 413.236(e), the MACs would follow a 2-step methodology for calculating a pre-adjusted per treatment amount.

Under the first step, the MACs would determine the annual allowance, that represents the amount of the MAC-determined price that is allocable to 1 year. To calculate the annual allowance, we propose that the MACs would use the straight-line depreciation method by dividing the MAC-determined price by the useful life of the home dialysis machine. In accordance with the straight-line depreciation method, the MAC would divide the MAC-determined price by 5 (the useful life for dialysis machines established by the AHA is 5 years).

Under the second step, the MACs would calculate a pre-adjusted per treatment amount by dividing the annual allowance by the expected number of treatments to yield a pre-adjusted per treatment amount. That is, the MACs would establish a pre-adjusted per treatment amount by dividing the annual allowance by the number of treatments expected to be furnished in a year. For home dialysis machines that are expected to be used 3 times per week, the annual number of treatments is 156 (3 treatments/week X 52 weeks = 156 treatments/year). We note, for purposes of calculating this TPNIES add-on payment adjustment, MACs do not determine the number of expected treatments. This information will be provided by CMS through the Change Request.

We note, below in section II.B.3.b.(3) of this proposed rule, we are considering an

alternative to our proposal. The alternative is a methodology that would offset the pre-adjusted per treatment amount by a value that would reflect the amount already included in the ESRD PPS base rate.

Finally, consistent with the policies finalized last year in § 413.236(d) for the TPNIES, we propose to revise § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount for capital-related assets that are home dialysis machines when used in the home for a single patient. That is, as discussed in the CY 2020 ESRD PPS final rule (84 FR 60692 through 60693), we finalized a policy to base the TPNIES payment on 65 percent of the MAC-determined price in order to maintain consistency with the IPPS NTAP payment policy and to mitigate the Medicare expenditures incurred as a result of the TPNIES. Therefore, we propose to pay 65 percent of the pre-adjusted per treatment amount for these machines.

For example, for a home dialysis machine that has a MAC-determined price of \$25,000 and a 5-year useful life, using the proposed straight-line depreciation method, the annual allowance would equate to \$5,000 per year. At 156 treatments per year, the pre-adjusted per treatment amount is \$32.05 ($\$5,000/156$) and 65 percent of that amount equals a TPNIES per treatment add-on payment amount of \$20.83 ($\$32.05 \times .65$). We note that at this time the useful life of 5 years and the expected number of treatments of 156 is fixed since these variables have been established by CMS. That is, as we discussed above in this section with regard to the use of the AHA guidance that dialysis machines have a 5-year useful life. With regard to the expected number of treatments, this is based on the current payment policy of 3 treatments per week.

In the future, if an innovative home dialysis machine is designed to require fewer treatments per week relative to existing machines, MACs, using the same methodology could account for fewer treatments in the denominator in the calculation of the pre-adjusted per

treatment amount. This change to the denominator would allow the total TPNIES amount paid at the end of the year to be equivalent to the annual allowance and we would then proceed with the calculation to achieve the targeted 65 percent of that annual allowance. The following example demonstrates that the annual allowance stays fixed even if there is a change in the number of treatments the machine is expected to deliver per year. The TPNIES payment adjustment would increase because the annual allowance would be spread over less treatments so that the targeted amount would pay out by the end of the year.

For a home dialysis machine that is used two times per week, using the same example as above, the annual allowance for TPNIES would remain at \$5,000 per year. Two treatments per week equals 104 treatments per year (2 treatments per week x 52 weeks = 104 treatments per year). The annual allowance (numerator) would be divided by the number of treatments (denominator). At 104 treatments per year, the pre-adjusted per treatment amount would be \$48.08 ($\$5,000/104 \text{ treatments} = \48.08); and 65 percent of that amount would yield a TPNIES per treatment add-on payment of \$31.25.

For a peritoneal dialysisycler that is used 7 times per week, using the same example as above, the annual allowance for TPNIES would remain at \$5,000 per year. A daily modality, or 7 treatments per week, equals 364 treatments per year (7 treatments per week x 52 weeks = 364 treatments per year). The annual allowance (numerator) would be divided by the number of treatments (denominator). At 364 treatments per year, the pre-adjusted per treatment amount would be \$13.74 ($\$5,000/364 \text{ treatments} = \13.74); and 65 percent of that amount would yield a TPNIES per treatment add-on payment of \$8.93.

The methodology is the same. The two variables, regardless of modality, are: (1) the cost of the machine used to calculate annual allowance (2) the number of treatments the machine is

expected to deliver per year.

We are inviting public comment on using this proposed method for determining the pricing of capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the eligibility criteria in § 413.236(b), including the proposed revisions discussed in section II.B.3.b.(1) of this proposed rule.

Consistent with the TPNIES policy and in accordance with § 413.236(d)(1), we would apply the TPNIES for these home dialysis machines for 2-calendar years from the effective date of the change request, which would coincide with the effective date of a CY ESRD PPS final rule. In the change request we would specify that the add-on payment adjustment would be applicable to home dialysis treatments and provide the billing guidance on how to report the miscellaneous code for the eligible item on the claim until a permanent HCPCS is available.

We believe the duration of the application of the TPNIES for all equipment and supplies determined eligible for this payment adjustment should be consistent, and 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 home dialysis machines. In addition, in light of the current COVID-19 pandemic, stakeholders are increasingly aware of the importance of having home dialysis readily available and in place to prevent ESRD patients from being exposed to asymptomatic or pre-symptomatic infections that contribute to COVID-19 transmission by having to utilize in-center dialysis.

We further believe providing the TPNIES for 2 years for these machines would address the stakeholders' concerns regarding additional payment to account for higher cost of more new and innovative home dialysis machines that they believe may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, this TPNIES would give these new and

innovative home dialysis machines a foothold in the market and the opportunity to compete with the other dialysis machines. We note that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary co-insurance, since we have not previously provided a payment adjustment for any capital-related assets in the past. However, to support HHS's goals and initiatives to increase home dialysis and the President's Executive Order of July 10, 2019, we believe that the proposed expansion of the TPNIES to capital-related assets that are home dialysis machines when used in the home for a single patient would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment to ESRD patients.

The intent of the proposed TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home would be to provide a transition period to support ESRD facility use of these machines when they are new and innovative to the market. 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 home dialysis machines because, as noted previously in this proposed rule, the ESRD PPS base rate includes the cost of equipment and supplies used to furnish a dialysis treatment.

While we would monitor renal dialysis service utilization trends during the TPNIES payment period, we propose that these capital-related assets that are home dialysis machines when used in the home would not be eligible outlier services as provided in § 413.237. As assets, capital-related home dialysis machines are distinct from operating expenses such as the disposable supplies and leased equipment with no conveyed ownership rights. These expenses are generally accounted for on a per patient basis and therefore, when used in excess of the average constitute outlier use, which makes them eligible for outlier payments.

Therefore, we are proposing revisions at § 413.236(d)(2) to reflect that following payment of the TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient, the ESRD PPS base rate will not be modified and the equipment would not be an eligible outlier service as provided in § 413.237. In addition, we propose revisions at § 413.237(a)(1)(v) to exclude capital-related assets that are home dialysis machines when used in the home for a single patient from outlier eligibility after the TPNIES period ends. We also propose minor editorial changes to paragraph (a)(1)(i) to remove the semicolon at the end of the sentence and adding a period in its place; and in paragraph (a)(1)(iv) to remove “; and” and adding a period in its place.

With regard to the TPNIES application, we would post any final changes to both the timing of the various eligibility criteria and the content of the TPNIES application to the TPNIES website, along with information about all renal dialysis equipment and supplies that CMS has determined are eligible for the TPNIES, consistent with the policies we finalize in the CY 2021 ESRD PPS final rule. The TPNIES website is available at:

<https://www.cms.gov/medicare/esrd-pps/esrd-pps-transitional-add-payment-adjustment-new-and-innovative-equipment-and-supplies-tpnies>.

(3) Alternative to Offset the Proposed Pre-Adjusted Per Treatment Amount

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.

In addition, as we discussed in section II.B.3.(a) of this proposed rule, these composite rate payments, and consequently the ESRD PPS base rate, include an amount associated with the costs of capital-related assets that are home dialysis machines. We believe that capital-related assets are distinguishable from drugs and biological products and supplies, which are single-use or disposable items, whereas ESRD facilities can continually use a home dialysis machine past its expected useful life and for multiple patients (consecutively). Therefore, we believe that an offset of the proposed TPNIES pre-adjusted per treatment amount may be warranted so that the TPNIES would cover the estimated marginal costs of new and innovative home dialysis machines. That is, ESRD facilities using the new and innovative home dialysis machine would receive a per treatment payment to cover some of the cost of the new machine per treatment minus a per treatment payment amount that we estimate to be included in the ESRD PPS base rate for current home dialysis machines that they already own.

To account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own, we are considering an alternative to our proposal that would include an additional step to calculating the TPNIES. That is, we could apply an offset to the pre-adjusted per treatment amount. The following section discusses the

methodology that we would use for determining the offset. If we were to adopt an offset in the final rule, we would add language to the proposed § 413.236(f) specifying the methodology used to compute the offset and its place—the final step—in the computation of the TPNIES for new and innovative home dialysis machines that meet the eligibility criteria.

(4) Methodology for Estimating Home Machine and Equipment Cost Per Home Treatment

As we stated in the previous section, we considered proposing an alternative to our proposed methodology for calculating the pre-adjusted per treatment amount, which would involve applying an offset to the pre-adjusted per treatment amount. This section discusses the methodology we would use for determining the value of that offset, which would be an estimate of an average home dialysis machine and equipment cost per hemodialysis (HD)-equivalent home dialysis treatment to use as the offset amount. First, we would estimate annualized dialysis machine and equipment cost and treatment counts from cost reports for each ESRD facility for 2018. Next, we would compute an HD-equivalent home dialysis treatment percentage for each ESRD facility by dividing the annualized HD-equivalent home treatment counts by the annualized HD-equivalent treatment counts across all modalities. Then we would apply the home dialysis treatment percentage to the annualized dialysis machine and equipment cost to derive an estimated home dialysis machine and equipment cost for each ESRD facility. Next, we would aggregate the home dialysis machine and equipment costs and the HD-equivalent home treatment counts to derive an average home dialysis machine and equipment cost per home dialysis treatment across all ESRD facilities. Finally, we would scale the 2018 average home dialysis machine and equipment cost per home treatment to 2021 using the ESRDB market basket less productivity update for CY 2019, CY 2020, and CY 2021.

We would obtain annualized dialysis machine and equipment cost and treatment counts from freestanding and hospital-based ESRD cost reports. For independent/freestanding ESRD facilities, we would use renal facility cost reports (CMS form 265-11). We would obtain dialysis machine and equipment cost⁷ from Worksheet B, Column 4, and sum up Lines 8.01 through 17.02. We would obtain dialysis treatment counts by modality from Worksheet D, Column 1, Lines 1 through 10. Since home continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) treatment counts are reported in patient weeks, we would multiply them by 3 to get HD-equivalent counts. Finally, we would aggregate all home dialysis treatment counts to obtain each ESRD facility's HD-equivalent home dialysis treatment counts and we would aggregate the treatment counts to obtain each freestanding ESRD facility's HD-equivalent dialysis treatment counts for all modalities.

For hospital-based ESRD facilities, we would use hospital cost reports (CMS form 2552-10). We would obtain dialysis machine and equipment cost from Worksheet I-2, Column 2, and then sum up Lines 2 through 11. We would derive dialysis treatment counts by modality from Worksheet I-4, Column 1, Lines 1 through 10. Home CAPD and CCPD treatment counts are reported in patient weeks, so we would multiply them by 3 to get HD-equivalent counts. We would aggregate all home treatment counts to obtain each hospital-based ESRD facility's HD-equivalent home dialysis treatment counts. Then we would aggregate all treatment counts to obtain each hospital-based ESRD facility's HD-equivalent dialysis treatment counts for all modalities.

⁷ Here dialysis machine and equipment cost includes capital-related costs of moveable equipment, rented and/or purchased, and maintenance on the dialysis machine and any support equipment. This also includes the equipment and associated maintenance and repair and installation costs necessary to render the water acceptable for use in dialysis.

Using this methodology for both freestanding and hospital-based ESRD facilities, it would result in an offset of \$9.23. If we were to adopt this approach, the MAC would apply this additional step in calculating the pre-adjusted per treatment amount. That is, the MAC would offset the pre-adjusted per treatment amount by deducting \$9.23 to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own. We believe that this methodology would provide an approximation of the cost of the home dialysis machine in the base rate. Further, we believe that deducting it from the calculated pre-adjusted per treatment amount would be reasonable because the beneficiary would not be using two home dialysis machines at the same time and at the end of the 2 years, the ESRD facility would retain ownership of the asset, specifically, the home dialysis machine.

Using the example from section II.B.3.b.(2), for a home dialysis machine that has a MAC-determined price of \$25,000 and a 5-year useful life, using the proposed straight-line depreciation method, the annual allowance would equate to \$5,000 per year. At 156 treatments per year, the pre-adjusted per treatment amount is \$32.05 ($\$5,000/156$). Under the alternative to our proposal, we would offset the pre-adjusted per treatment amount of \$32.05 by deducting \$9.23. This would result in a per treatment amount of \$22.82 ($\$32.05 - \9.23). Then 65 percent of that amount would equal a TPNIES per treatment add-on payment amount of \$14.83 ($\$22.82 \times .65$). After the TPNIES per treatment add-on payment amount is determined, there would be no change in the policy as described in section II.B.3.b.(2) with regard to the TPNIES duration, process, and the ESRD PPS base rate, that is, no change to the base rate would be made.

We are soliciting comment on this alternative approach to apply an offset to the proposed pre-adjusted per treatment amount. We are specifically soliciting comment on the methodology we would use to compute the value of the offset.

4. Proposed CY 2021 ESRD PPS Update

a. Proposed CY 2021 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share

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 2021 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 2020 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2019), the proposed CY 2021 ESRDB market basket increase factor is 2.2 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 2020 forecast, the proposed MFP adjustment for CY 2021

(the 10-year moving average of MFP for the period ending CY 2021) is projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2021 ESRD market basket adjusted for MFP is 1.8 percent (2.2 – 0.4). This market basket increase is calculated by starting with the proposed CY 2021 ESRDB market basket percentage increase factor of 2.2 percent and reducing it by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending CY 2021) of 0.4 percent.

As is our general practice, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket update or MFP), we would use such data, if appropriate, to determine the final CY 2021 market basket update and/or MFP adjustment.

For the CY 2021 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 2021 ESRD PPS Wage Indices

(1) Background

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/information-for-agencies/bulletins/>.

For CY 2021, 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. For CY 2021, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2016 and before October 1, 2017 (FY 2017 cost report data).

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 to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we 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). We note that for the CY 2020 ESRD PPS final rule, we did not apply the statewide urban average to Carson City, Nevada because hospital data was available to compute the wage index.

A wage index floor value (0.5000) 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. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD 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 2021, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

For CY 2021, in addition to proposing to update the ESRD PPS wage index to use more recent hospital wage data, we are also proposing to adopt new OMB delineations and a transition policy in a budget-neutral manner as discussed in sections II.B.4.b.(2) and II.B.4.b.(3), respectively, of this proposed rule. The proposed CY 2021 ESRD PPS wage index is set forth in Addendum A and is available 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>. Addendum A provides a crosswalk between the CY 2020 wage index for an ESRD facility using the current OMB delineations in effect in CY 2020, the CY 2021 wage

index using the current OMB delineations in effect in CY 2020, and the CY 2021 wage index using the proposed new OMB delineations. Addendum B provides an ESRD facility-level impact analysis. In Addendum B are the proposed transition wage index values that would be in effect in CY 2021 if these proposed changes are finalized. Addendum B is available 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>.

(2) Proposed Implementation of New OMB Labor Market Delineations

As discussed previously in this proposed rule, the wage index used for the ESRD PPS is calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS and is assigned to an ESRD facility on the basis of the labor market area in which the ESRD facility is geographically located. ESRD facility labor market areas are delineated based on the CBSAs established by the OMB. In accordance with our established methodology, we have historically adopted through rulemaking CBSA changes that are published in the latest OMB bulletin. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses.

In the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we finalized changes to the ESRD PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13-01⁸ issued on February 28, 2013. We implemented these changes with a 2-year transition period (79 FR 66142). OMB Bulletin No. 13-01 established revised delineations for U.S. Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical

⁸ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf>

Areas based on the 2010 Census. OMB Bulletin No. 13-01 also provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252).

On July 15, 2015, OMB issued OMB Bulletin No. 15-01,⁹ which updated and superseded OMB Bulletin No. 13-01 issued on February 28, 2013. The attachment to OMB Bulletin No. 15-01 provided detailed information on the update to statistical areas since February 28, 2013. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2012 and July 1, 2013.

On August 15, 2017, OMB issued OMB Bulletin No. 17-01,¹⁰ which updated and superseded OMB Bulletin No. 15-01 issued on July 15, 2015. The attachment to OMB Bulletin No. 17-01 provided detailed information on the update to statistical areas since July 15, 2015. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17-01, OMB announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300).

On April 10, 2018, OMB issued OMB Bulletin No. 18-03¹¹ which updated and superseded OMB Bulletin No. 17-01 issued on August 15, 2017. The attachment to OMB Bulletin No. 18-03 provided detailed information on the update to statistical areas since August 15, 2017. On September 14, 2018, OMB issued OMB Bulletin No. 18-04,¹² which updated and

⁹ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf>

¹⁰ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>

¹¹ <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>

¹² <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>

superseded OMB Bulletin No. 18-03 issued on April 10, 2018. OMB Bulletin Numbers 18-03 and 18-04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2015 and July 1, 2016.

While OMB Bulletin No. 18-04 is not based on new census data, there were some material changes to the CBSA-based geographic area designations based on the new OMB delineations. For example, if we adopt the new OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs would be split apart. We believe that the new OMB delineations accurately reflect the local economies and wage levels of the areas where ESRD facilities are located. We believe it is important for the ESRD PPS to use the new OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the new OMB delineations would increase the integrity of the ESRD PPS wage index system by creating a more accurate representation of geographic variations in wage levels.

Therefore, we are proposing to adopt the new OMB delineations established in OMB Bulletin No. 18-04 effective for CY 2021 under the ESRD PPS. We are also proposing a wage index transition applicable to all ESRD facilities that experience negative impacts due to the proposed implementation of the new OMB delineations. This transition policy is discussed in section II.B.4.b.(3) of this proposed rule.

We note that, on March 6, 2020, OMB issued OMB Bulletin 20-01 (available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>). While the March 6, 2020 OMB Bulletin 20-01 was not issued in time for development of this proposed rule, we were able to review the updates it provides and have determined that they are minor. While we do not believe the minor updates included in OMB Bulletin 20-01 would impact our CY 2021 proposed updates to the CBSA-based labor market area delineations, if appropriate, we would propose any updates from this Bulletin in the CY 2022 ESRD PPS proposed rule.

For CY 2021, to implement the new OMB delineations established in OMB Bulletin No. 18-04 under the ESRD PPS, it is necessary to identify the new labor market area delineation for each affected county and ESRD facility in the U.S. We discuss these changes in more detail in the following sections.

(a) Urban Counties That Would Become Rural Under the New OMB Delineations

As previously discussed in this proposed rule, we are proposing to implement the new OMB labor market area delineations (based upon the 2010 Decennial Census data) beginning in CY 2021. Our analysis of the new OMB delineations shows that a total of 34 counties (and county equivalents) that are currently considered part of an urban CBSA would be considered located in a rural area, beginning in CY 2021. Table 1 shows the 34 urban counties that would be rural if we finalize our proposal to adopt the new OMB delineations beginning in CY 2021.

TABLE 1: CY 2021 Proposed Urban to Rural CBSA Crosswalk

FIPS County Code	County/County Equivalent	State	Current CBSA	CBSA Title
01127	WALKER	AL	13820	Birmingham-Hoover, AL
12045	GULF	FL	37460	Panama City, FL
13007	BAKER	GA	10500	Albany, GA
13235	PULASKI	GA	47580	Warner Robins, GA
15005	KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI

FIPS County Code	County/County Equivalent	State	Current CBSA	CBSA Title
17039	DE WITT	IL	14010	Bloomington, IL
17053	FORD	IL	16580	Champaign-Urbana, IL
18143	SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
18179	WELLS	IN	23060	Fort Wayne, IN
19149	PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
20095	KINGMAN	KS	48620	Wichita, KS
21223	TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
22119	WEBSTER	LA	43340	Shreveport-Bossier City, LA
26015	BARRY	MI	24340	Grand Rapids-Wyoming, MI
26159	VAN BUREN	MI	28020	Kalamazoo-Portage, MI
27143	SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
28009	BENTON	MS	32820	Memphis, TN-MS-AR
29119	MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
30037	GOLDEN VALLEY	MT	13740	Billings, MT
31081	HAMILTON	NE	24260	Grand Island, NE
38085	SIOUX	ND	13900	Bismarck, ND
40079	LE FLORE	OK	22900	Fort Smith, AR-OK
45087	UNION	SC	43900	Spartanburg, SC
46033	CUSTER	SD	39660	Rapid City, SD
47081	HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	ARANSAS	TX	18580	Corpus Christi, TX
48221	HOOD	TX	23104	Fort Worth-Arlington, TX
48351	NEWTON	TX	13140	Beaumont-Port Arthur, TX
48425	SOMERVELL	TX	23104	Fort Worth-Arlington, TX
51029	BUCKINGHAM	VA	16820	Charlottesville, VA
51033	CAROLINE	VA	40060	Richmond, VA
51063	FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
53013	COLUMBIA	WA	47460	Walla Walla, WA
53051	PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA

We are proposing that the wage data for all ESRD facilities located in the counties listed above would now be considered rural, beginning in CY 2021, when calculating their respective State's rural wage index. We recognize that rural areas typically have lower area wage index values than urban areas, and ESRD facilities located in these counties may experience a negative

impact in their payment under the ESRD PPS due to the proposed adoption of the new OMB delineations. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

(b) Rural Counties That Would Become Urban Under the New OMB Delineations

As previously discussed in this proposed rule, we are proposing to implement the new OMB labor market area delineations (based upon the 2010 Decennial Census data) beginning in CY 2021. Our analysis of the new OMB delineations shows that a total of 47 counties (and county equivalents) that are currently considered located in rural areas would be considered located in urban CBSAs, beginning in CY 2021. Table 2 shows the 47 rural counties that would be urban if we finalize our proposal to adopt the new OMB delineations beginning in CY 2021.

TABLE 2: CY 2021 Proposed Rural to Urban CBSA Crosswalk

FIPS County Code	County/County Equivalent	State Name	Proposed CBSA	Proposed CBSA Title
01063	GREENE	AL	46220	Tuscaloosa, AL
01129	WASHINGTON	AL	33660	Mobile, AL
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
12075	LEVY	FL	23540	Gainesville, FL
13259	STEWART	GA	17980	Columbus, GA-AL
13263	TALBOT	GA	17980	Columbus, GA-AL
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
18047	FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
18121	PARKE	IN	45460	Terre Haute, IN
18171	WARREN	IN	29200	Lafayette-West Lafayette, IN
19015	BOONE	IA	11180	Ames, IA
19099	JASPER	IA	19780	Des Moines-West Des Moines, IA
20061	GEARY	KS	31740	Manhattan, KS
21043	CARTER	KY	26580	Huntington-Ashland, WV-KY-OH
22007	ASSUMPTION	LA	12940	Baton Rouge, LA
22067	MOREHOUSE	LA	33740	Monroe, LA
25011	FRANKLIN	MA	44140	Springfield, MA
26067	IONIA	MI	24340	Grand Rapids-Kentwood, MI

FIPS County Code	County/County Equivalent	State Name	Proposed CBSA	Proposed CBSA Title
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
28051	HOLMES	MS	27140	Jackson, MS
28131	STONE	MS	25060	Gulfport-Biloxi, MS
29053	COOPER	MO	17860	Columbia, MO
29089	HOWARD	MO	17860	Columbia, MO
30095	STILLWATER	MT	13740	Billings, MT
37007	ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
37029	CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
39123	OTTAWA	OH	45780	Toledo, OH
45027	CLARENDON	SC	44940	Sumter, SC
47053	GIBSON	TN	27180	Jackson, TN
47161	STEWART	TN	17300	Clarksville, TN-KY
48203	HARRISON	TX	30980	Longview, TX
48431	STERLING	TX	41660	San Angelo, TX
51097	KING AND QUEEN	VA	40060	Richmond, VA
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54065	MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR

We are proposing that when calculating the area wage index, beginning with CY 2021, the wage data for ESRD facilities located in these counties would be included in their new respective urban CBSAs. Typically, ESRD facilities located in an urban area receive a higher wage index value than or equal wage index value to ESRD facilities located in their state's rural

area. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

(c) Urban Counties That Would Move to a Different Urban CBSA Under the New OMB Delineations

In certain cases, adopting the new OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) would experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. Table 3 shows the current CBSA code and our proposed CBSA code where we are proposing to change either the name or CBSA number only.

TABLE 3: CY 2021 Proposed Change in CBSA Name and/or Number Crosswalk

Current CBSA Code	Current CBSA Title	Proposed CBSA Code	Proposed CBSA Title
10540	Albany, OR	10540	Albany-Lebanon, OR
11500	Anniston-Oxford-Jacksonville, AL	11500	Anniston-Oxford, AL
12060	Atlanta-Sandy Springs-Roswell, GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
12420	Austin-Round Rock, TX	12420	Austin-Round Rock-Georgetown, TX
13460	Bend-Redmond, OR	13460	Bend, OR
13980	Blacksburg-Christiansburg-Radford, VA	13980	Blacksburg-Christiansburg, VA
14740	Bremerton-Silverdale, WA	14740	Bremerton-Silverdale-Port Orchard, WA
15380	Buffalo-Cheektowaga-Niagara Falls, NY	15380	Buffalo-Cheektowaga, NY
19430	Dayton-Kettering, OH	19380	Dayton, OH
24340	Grand Rapids-Wyoming, MI	24340	Grand Rapids-Kentwood, MI

Current CBSA Code	Current CBSA Title	Proposed CBSA Code	Proposed CBSA Title
24860	Greenville-Anderson-Mauldin, SC	24860	Greenville-Anderson, SC
25060	Gulfport-Biloxi-Pascagoula, MS	25060	Gulfport-Biloxi, MS
25540	Hartford-West Hartford-East Hartford, CT	25540	Hartford-East Hartford-Middletown, CT
25940	Hilton Head Island-Bluffton-Beaufort, SC	25940	Hilton Head Island-Bluffton, SC
28700	Kingsport-Bristol-Bristol, TN-VA	28700	Kingsport-Bristol, TN-VA
31860	Mankato-North Mankato, MN	31860	Mankato, MN
33340	Milwaukee-Waukesha-West Allis, WI	33340	Milwaukee-Waukesha, WI
34940	Naples-Immokalee-Marco Island, FL	34940	Naples-Marco Island, FL
35660	Niles-Benton Harbor, MI	35660	Niles, MI
36084	Oakland-Hayward-Berkeley, CA	36084	Oakland-Berkeley-Livermore, CA
36500	Olympia-Tumwater, WA	36500	Olympia-Lacey-Tumwater, WA
38060	Phoenix-Mesa-Scottsdale, AZ	38060	Phoenix-Mesa-Chandler, AZ
39150	Prescott Valley-Prescott, AZ	39140	Prescott, AZ
23224	Frederick-Gaithersburg-Rockville, MD	43524	Silver Spring-Frederick-Rockville, MD
44420	Staunton-Waynesboro, VA	44420	Staunton, VA
44700	Stockton-Lodi, CA	44700	Stockton, CA
45940	Trenton, NJ	45940	Trenton-Princeton, NJ
46700	Vallejo-Fairfield, CA	46700	Vallejo, CA
47300	Visalia-Porterville, CA	47300	Visalia, CA
48140	Wausau, WI	48140	Wausau-Weston, WI
48424	West Palm Beach-Boca Raton-Delray Beach, FL	48424	West Palm Beach-Boca Raton-Boynton Beach, FL

As we explained previously in this proposed rule, ESRD facilities located in an urban area that, due to the new OMB delineations, involves a change only in the CBSA name or number would not experience a consequential change in their wage index value.

However, in other cases, if we adopt the new OMB delineations, counties would shift

between existing and new CBSAs, changing the constituent makeup of the CBSAs. We consider these types of changes, where CBSAs are split into multiple new CBSAs or a CBSA loses one or more counties to another urban CBSAs, to be significant modifications.

Table 4 (CY 2021 Proposed Urban to a Different Urban CBSA Crosswalk) shows the urban counties that would move from one urban CBSA to another a newly proposed or modified CBSA, if we adopt the new OMB delineations.

TABLE 4: CY 2021 Proposed Urban to a Different Urban CBSA Crosswalk

FIPS County Code	County/ County Equivalent	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
17031	COOK	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17043	DU PAGE	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17063	GRUNDY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17093	KENDALL	IL	16974	Chicago-Naperville-Arlington Heights, IL	20994	Elgin, IL
17111	MC HENRY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17197	WILL	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
34023	MIDDLESEX	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34025	MONMOUTH	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34029	OCEAN	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34035	SOMERSET	NJ	35084	Newark, NJ-PA	35154	New Brunswick-Lakewood, NJ
36027	DUTCHESS	NY	20524	Dutchess County-Putnam County, NY	39100	Poughkeepsie-Newburgh-Middletown, NY
36071	ORANGE	NY	35614	New York-Jersey City-White Plains, NY-NJ	39100	Poughkeepsie-Newburgh-Middletown, NY
36079	PUTNAM	NY	20524	Dutchess County-Putnam County, NY	35614	New York-Jersey City-White Plains, NY-NJ
47057	GRAINGER	TN	28940	Knoxville, TN	34100	Morristown, TN
54043	LINCOLN	WV	26580	Huntington-Ashland, WV-KY-OH	16620	Charleston, WV
72055	GUANICA	PR	38660	Ponce, PR	49500	Yauco, PR
72059	GUAYANILLA	PR	38660	Ponce, PR	49500	Yauco, PR

FIPS County Code	County/ County Equivalent	State	Current CBSA	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
72111	PENUELAS	PR	38660	Ponce, PR	49500	Yauco, PR
72153	YAUCO	PR	38660	Ponce, PR	49500	Yauco, PR

If ESRD facilities located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, to their specific wage index values. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

(d) Changes to the Statewide Rural Wage Index

ESRD facilities currently located in a rural area may remain rural under the new OMB delineations but experience a change in their rural wage index value due to the movement of constituent counties. If ESRD facilities located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. A discussion of the proposed wage index transition policy due to these proposed changes is available in section II.B.4.b.(3) of this proposed rule.

We believe these revisions to the CBSA-based labor market area delineations as established in OMB Bulletin 18-04 would ensure that the ESRD PPS area wage level adjustment most appropriately accounts for and reflects the relative wage levels in the geographic area of the ESRD facility. Therefore, we are proposing to adopt the new OMB delineations under the ESRD PPS, effective January 1, 2021.

We invite public comment on the proposal to adopt the new OMB delineations, effective beginning with the CY 2021 ESRD PPS wage index.

(3) Proposed Transition for ESRD Facilities Negatively Impacted

To mitigate the potential impacts of proposed policies on ESRD facilities, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget-neutral transition policies to help mitigate negative impacts on ESRD facilities following the adoption of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 (79 FR 66142). Specifically, as part of the CY 2015 ESRD PPS rulemaking, we implemented a 2-year transition blended wage index for all ESRD facilities. ESRD facilities received 50 percent of their CY 2015 wage index value based on the OMB delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the new OMB delineations. This resulted in an average of the two values. Then, in CY 2016, an ESRD facility's wage index value was based 100 percent on the new OMB delineations.

We considered having no transition period and fully implementing the proposed new OMB delineations beginning in CY 2021, which would mean that all ESRD facilities would have payments based on updated hospital wage data and the new OMB delineations starting on January 1, 2021. However, because the overall amount of ESRD PPS payments would increase slightly due to the new OMB delineations, the wage index budget neutrality factor would be higher. This higher factor would reduce the ESRD PPS per treatment base rate for all ESRD facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities would be unaffected by the new OMB delineations. Thus, we believe it would be appropriate to provide for a transition period to mitigate the resulting short-term instability of a lower ESRD PPS base rate as well as consequential negative impacts to ESRD facilities that experience reduced payments. For example, ESRD facilities currently located in CBSA 35614 (New York-Jersey City-White Plains, NY-NJ) that would be located in new CBSA 35154 (New Brunswick-

Lakewood, NJ) under the proposed changes to the OMB delineations would experience a nearly 17 percent decrease in the wage index as a result of the proposed change.

Therefore, under the authority of section 1881(b)(14)(D)(iv)(II) of the Act and consistent with past practice, we are proposing a transition policy to help mitigate any significant, negative impacts that ESRD facilities may experience due to our proposal to adopt the new OMB delineations under the ESRD PPS. Specifically, as a transition for CY 2021, we are proposing to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would allow the effects of our proposed adoption of the new OMB delineations to be phased in over 2 years, where the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. We believe a 5 percent cap on the overall decrease in an ESRD facility's wage index value, regardless of the circumstance causing the decline, would be an appropriate transition for CY 2021 as it would provide predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than our prior 2-year 50/50 blended wage index approach. We believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. We solicit comment on the proposal to apply a 5 percent cap on any decrease in an ESRD facility's wage index for CY 2021 from the ESRD facility's wage index from the prior calendar year, CY 2020.

(4) Proposed Budget Neutrality Adjustments for Changes to the ESRD PPS Wage Index

Consistent with the historical wage index budget-neutrality adjustment policy finalized in the CY 2012 ESRD PPS final rule (76 FR 70241 through 70242) under the authority of section

1881(b)(14)(D)(iv)(II) of the Act, we are proposing that the proposed adoption of the new OMB delineations and the proposed transition policy would not result in any change of estimated aggregate ESRD PPS payments by applying a budget neutrality factor to the ESRD PPS base rate. We note budget neutrality was also applied to the adoption of new OMB delineations and transition policy in the CY 2015 ESRD PPS final rule (79 FR 66128 through 66129). Our proposed methodology for calculating this proposed budget neutrality factor is discussed in section II.B.4.d.(2) of this proposed rule.

The proposed CY 2021 ESRD PPS wage index is set forth in Addendum A and is available 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>. Addendum A provides a crosswalk between the CY 2020 wage index for an ESRD facility using the current OMB delineations in effect in CY 2020, the CY 2021 wage index using the current OMB delineations in effect in CY 2020, and the CY 2021 wage index using the proposed new OMB delineations. Addendum B provides an ESRD facility-level impact analysis. In Addendum B are the proposed transition wage index values that would be in effect in CY 2021 if these proposed changes are finalized. Addendum B is available 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>.

c. Proposed CY 2021 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 secondary hyperparathyroidism. 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) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) 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; (4) 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 (5) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

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 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 Medicare allowable payment (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 fixed-dollar loss (FDL) amount. In accordance with § 413.237(c), 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 used to compute the payment adjustments.

In the CY 2020 ESRD PPS final rule (84 FR 60705), we stated that based on the CY 2018 claims data, outlier payments represented approximately 0.5 percent of total payments. We also noted that, beginning in CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy. We projected that for each dialysis treatment furnished, the average amount attributed to the TDAPA was \$21.03 (84 FR 60704).

For CY 2021, we propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2019. 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 2021 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2019. We note that, for CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy (calculated to be \$14.87 per treatment). However, as discussed in section II.B.1 of this proposed rule, for CY 2021 we propose to modify the ESRD PPS base rate by adding \$12.06 to account for calcimimetics in the ESRD PPS bundled payment and no longer pay for these drugs using the TDAPA. In addition, we are proposing that beginning January 1, 2021, calcimimetics would be eligible outlier services.

As discussed in section II.B.4.c.(2) of this proposed rule, CY 2019 claims data show outlier payments represented approximately 0.5 percent of total payments. 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. For CY 2021, the predicted outlier services MAP amounts and FDL amounts have increased as a result of our proposal to incorporate oral and injectable calcimimetics into the outlier policy.

(1) CY 2021 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2021, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2019 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2019 claims data. The impact of this update is shown in Table 5, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2020 with the updated proposed estimates for this rule. The estimates for the proposed CY 2021

outlier policy, which are included in Column II of Table 5, were inflation adjusted to reflect projected 2021 prices for outlier services.

TABLE 5: Outlier Policy: Impact of Using Updated Data to Define the Outlier Policy

	Column I Final outlier policy for CY 2020 (based on 2018 data, price inflated to 2020)*		Column II Proposed outlier policy for CY 2021 (based on 2019 data, price inflated to 2021)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	\$30.95	\$37.33	\$32.12	\$56.50
Adjustments				
Standardization for outlier services	1.0655	0.9781	1.0509	0.9801
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$32.32	\$35.78	\$33.08	\$54.26
FDL amount that is added to the predicted MAP to determine the outlier threshold	\$41.04	\$48.33	\$47.73	\$133.52
Patient-months qualifying for outlier payment	11.35%	10.38%	8.65%	4.91%

*Note that Column I was obtained from Column II of Table 2 from the CY 2020 ESRD PPS final rule (84 FR 60705).

As demonstrated in Table 5, the estimated FDL amount per treatment that determines the CY 2021 outlier threshold amount for adults (Column II; \$133.52) is higher than that used for the CY 2020 outlier policy (Column I; \$48.33). The higher threshold is accompanied by an increase in the adjusted average MAP for outlier services from \$35.78 to \$54.26. For pediatric patients, there is an increase in the FDL amount from \$41.04 to \$47.73. There is a corresponding increase in the adjusted average MAP for outlier services among pediatric patients, from \$32.32 to \$33.08.

As we stated previously, the predicted outlier services MAP amounts and FDL amounts have increased as a result of our proposal to incorporate oral and injectable

calcimimetics into the outlier policy. Approximately 30 percent of ESRD beneficiaries receive calcimimetics and a subset of these beneficiaries tend to have the highest ESRD PPS expenditures, which trigger outlier payments under the ESRD PPS. Since the highest per-beneficiary ESRD PPS expenditures would increase under our proposal for calcimimetics to become eligible ESRD outlier services, the outlier FDL would increase to ensure that total outlier payments project to 1 percent of total Medicare ESRD PPS expenditures.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2021 would be 4.91 percent for adult patients and 8.65 percent for pediatric patients, based on the 2019 claims data. The 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 calcimimetics, ESAs and other injectable drugs).

(2) 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 2019 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 2019 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2021.

We believe the update to the outlier MAP and FDL amounts for CY 2021 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. The

proposed inclusion of calcimimetics as ESRD outlier services in CY 2021 would fundamentally change the per-treatment distribution of outlier services relative to previous CYs. In 2019 claims, roughly 33 percent of ESRD beneficiaries and 28 percent of dialysis treatments are associated with calcimimetics and those that often have significantly higher utilization of ESRD outlier services relative to beneficiaries who do not receive calcimimetics. The MAP and FDL increases account for this change. 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.

d. Proposed Impacts to the CY 2021 ESRD PPS Base Rate

(1) 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, and the TPNIES.

(2) Annual Payment Rate Update for CY 2021

We are proposing an ESRD PPS base rate for CY 2021 of \$255.59. This update reflects several factors, described in more detail as follows:

- 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 2021, 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 2021 wage index budget-neutrality adjustment factor using treatment counts from the 2019 claims and facility-specific CY 2020 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2020. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2021. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD PPS wage index for CY 2021. As discussed in section II.B.4.b of this proposed rule, the proposed ESRD PPS wage index for CY 2021 includes an update to the most recent hospital wage data, the proposed adoption of the new OMB delineations, and a 5 percent cap on wage index decreases applied for CY 2021. The total of these payments becomes the new CY 2021 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 2021 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2021 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 2021 proposed wage index budget-neutrality adjustment factor is .998652. This application would yield a CY 2021 ESRD PPS proposed base rate of \$239.01, ($\$239.33 \times .998652 = \239.01), prior to the proposed addition to the ESRD PPS base rate to include calcimimetics and the application of the proposed market basket increase.

- Addition to the ESRD PPS Base Rate to Include Calcimimetics: As discussed in section II.B.1 of this proposed rule, for CY 2021 we are proposing to modify the ESRD PPS base rate by adding \$12.06 to account for calcimimetics in the ESRD PPS bundled payment. This application would yield a CY 2021 ESRD PPS proposed base rate of \$251.07 ($\$239.01 + \$12.06 = \251.07), prior to the application of the proposed market basket increase.

- 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 2021 projection for the proposed ESRDB market basket is 2.2 percent. In CY 2021, 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 2021 is 0.4 percent, thus yielding a proposed update to the base rate of 1.8 percent for CY 2021. Therefore, the CY 2021 ESRD PPS proposed base rate is \$255.59 ($\$251.07 \times 1.018 = \255.59).

In summary, we are proposing a CY 2021 ESRD PPS base rate of \$255.59. This

amount reflects a proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed addition of \$12.06 to the ESRD PPS base rate to include calcimimetics, and the CY 2021 ESRD PPS payment update of 1.8 percent.

5. Proposed Changes to the Low-Volume Payment Adjustment

a. Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS includes a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. We have established a LVPA factor of 23.9 percent for ESRD facilities that meet the definition of a low-volume facility. Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question.

For purposes of determining eligibility for the LVPA, “treatments” mean total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare as well as ESRD and

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

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. The attestation is required because: (1) ESRD facility's cost reporting periods vary and may not be based on the calendar year; and (2) the cost reports are due 5 months after the close of the cost reporting period (that is, there is a lag in the cost reporting submission). Thus, the MACs may not have the cost report for the third year to determine eligibility and would need to rely on the attestation for that year until the cost report is available. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions, with a few exceptions where the deadline is December 31. The November 1 timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236).

As stated in the Medicare Benefit Policy Manual, (Pub. L. 100-02), (chapter 11, section 60.B.1)¹³, once the attested ESRD facility's cost report is submitted to the MAC, the MAC verifies the as-filed cost report for the third eligibility year and finds that the ESRD facility met the eligibility criteria, the ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. However, if the attested ESRD facility's cost report for the third eligibility year exceeds the total dialysis treatment

¹³ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>

threshold, then the MAC recoups by reprocessing claims paid during the payment year in which the ESRD facility incorrectly received the LVPA. Recoupment also occurs if any cost reports used for eligibility are subsequently found to have not met the low-volume criteria, for example, reopening or appeals.

Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, chapter 11, section 60.B.1¹⁴.

b. Revisions to the LVPA Requirements and Regulations

As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56949), we have heard from stakeholders that low-volume facilities rely on the low-volume adjustment and loss of the adjustment could result in beneficiary access issues. Specifically, stakeholders expressed concern that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility in certain circumstances.

As discussed in section II.B.2 of this proposed rule, according to the Centers for Disease Control and Prevention (CDC), the risk factors for COVID-19 include older adults and people of any age who have serious underlying medical conditions, such as diabetes and chronic kidney disease undergoing dialysis. Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID-19. As a result, ESRD facilities are working together to keep the risk of spreading COVID-19 down as much as possible by shifting patients among the ESRD facilities in the same area. In some cases, this shifting of patients has caused some low-volume ESRD facilities to temporarily dialyze patients that they otherwise would not have dialyzed if there had not been a PHE. In addition, since cases of acute kidney injury (AKI) have increased in certain areas of the country due to

¹⁴ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>

COVID-19, there is also an increase in the number of patients discharged that need outpatient dialysis for some period of time while their kidneys regain normal function. We are concerned that these increases in dialysis treatments due to the COVID-19 PHE in CY 2020 may put certain low-volume facilities over the LVPA's treatment threshold causing the loss of, or the inability to qualify for, the 23.9 percent per treatment payment adjustment for payment years 2021, 2022, and 2023. We note that in CY 2020, 338 ESRD facilities receive the LVPA. We also note that in a typical year, we estimate that between 50-60 facilities lose their LVPA status. That is, there are between 50-60 ESRD facilities that typically lose their LVPA status because their patient population grew for reasons other than the COVID-19 PHE.

In light of the unique circumstance due to the COVID-19 PHE, we are proposing to hold ESRD facilities harmless if an increase in their treatment counts in 2020 is COVID-19-related such that the increase would prevent them from qualifying for the LVPA. We propose that the ESRD facility would attest that the increase in treatments, meaning total HD equivalent treatments (for ESRD and AKI), was temporary and related to the redistribution of patients in response to the COVID-19 PHE. When this occurs, instead of using total dialysis treatments furnished in cost reporting periods ending in 2020, CMS would rely on the facility's attestation that the increase in total dialysis treatments was due to the PHE for the COVID-19 pandemic. We propose for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, we would only consider total dialysis treatments furnished for 6 months of a facility's cost-reporting period ending in 2020, and that an ESRD facility would decide which 6 months to use (consecutive or non-consecutive) for purposes of reporting total treatments. That is, ESRD facilities would attest that, while it

furnished 4,000 or more treatments in its cost-reporting period ending in 2020, the number of treatments exceeding the allowed threshold to otherwise qualify for the LVPA was due to temporary patient shifting as a result of the COVID-19 PHE, and that their total dialysis treatments for any 6 months of that period is less than 2,000. MACs would annualize the total dialysis treatments for those 6 months by multiplying by 2. ESRD facilities would be expected to provide supporting documentation to the MACs upon request.

This proposal is responsive to requests we have received from stakeholders, and would prevent the loss of, or the inability to qualify for, the LVPA for facilities who accommodated additional patients in 2020 because of the COVID-19 PHE. We believe this proposal targets just those facilities that would not qualify for the LVPA for the reason that they accommodated additional patients in response to the COVID-19 PHE to, for example, prevent the spread of the infection.

We propose to revise § 413.232(g) by adding paragraph (g)(4) to reflect that, for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, an ESRD facility's attestation must indicate that the ESRD facility meets all the LVPA criteria except that, for a facility that does not otherwise meet the number-of-treatments criterion (that is, less than 4,000 in a year) because of the COVID-19 PHE, the facility furnished less than 2,000 treatments in any 6 months during its cost-reporting period ending in 2020 due to temporary patient shifting as a result of the COVID-19 PHE. We also propose that the MAC would rely on the facility's attestation and would annualize the total dialysis treatments for the 6 months by multiplying those collective 6 month treatments by 2.

In addition, since CMS changed cost reporting deadlines due to the COVID-19 PHE, we believe the extraordinary circumstances of the COVID-19 pandemic justify an exception to the

November 1, 2020 attestation deadline. Therefore, for payment year 2021, we propose to allow more time for ESRD facilities to submit attestations by extending the deadline to December 31, 2020. We would reflect this change in § 413.232(e) by reformatting the section to reflect already established exceptions to the November 1 attestation deadline in paragraphs (e)(1) through (3), and to include in new paragraph (e)(4) that, for payment year 2021, the attestation must be provided by December 31, 2020.

We are proposing a technical change at § 413.232(b) to remove the heading “Definition of low-volume facility” to be consistent with the current CFR requirements.¹⁵

We are also proposing a technical change at § 413.232(e) and (g). We propose to add “MAC” in § 413.232(e) to establish the acronym for Medicare Administrative Contractor. We propose to replace “Medicare Administrative Contractor (MAC)” with “MAC” in § 413.232(g) since the acronym would now be established in § 413.232(e).

c. Clarification for MAC LVPA Determinations

As we discuss in section II.B.5.(a) of this proposed rule, in order to receive the LVPA, an ESRD facility must meet the requirements of § 413.232, including submitting attestations to the MACs indicating its eligibility for the adjustment. In its attestation for the third eligibility year, which is the cost-reporting year immediately preceding the payment year, a facility attests that it will be eligible for the adjustment; this attestation typically occurs prior to the MAC having the facility’s cost report for the third eligibility year, in which case the MAC relies on the facility’s attestation to determine if the facility qualifies for the LVPA. When an ESRD facility qualifies for the adjustment, the LVPA would be

¹⁵ Document Drafting Handbook, chapter 2, section 2.10, page 2-18: <https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf>.

applied to all the Medicare-eligible treatments for the entire payment year. If the MAC subsequently determines, however, that the ESRD facility failed to qualify for the LVPA, and the facility had already begun to receive the adjustment to which the MAC has determined it is not entitled, the MAC would reprocess the claims to remove and recoup the low-volume payments.

We understand that in some instances, MACs may be discontinuing LVPA payments to a facility in the payment year for which the facility is eligible for the adjustment. However, the established policy is such that, if an ESRD facility meets the LVPA eligibility criteria in § 413.232, it is entitled to the payment adjustment for the entire payment year. Because there may be some inconsistent application of this policy, we are taking this opportunity to make this aspect of the LVPA policy clear in the regulation text.

We propose to revise § 413.232 by adding paragraph (h) to specify that, if an ESRD facility provides an attestation in accordance with § 413.232(e) for the third eligibility year, the MAC verifies the as-filed cost report. If the MAC determines an ESRD facility meets the definition of a low-volume facility, CMS adjusts the low-volume facility's base rate for the entire payment year. However, if the MAC determines an ESRD facility does not meet the definition of a low-volume facility, the MAC reprocesses claims and recoups low volume adjustments paid during the payment year.

C. Proposed Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies for CY 2021 Payment

1. Background

As we discussed in section II.B.2.a in the CY 2020 ESRD PPS final rule, we finalized the establishment of a transitional add-on payment adjustment for new and innovative equipment

and supplies (TPNIES) to support ESRD facilities in the uptake of certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. Under our current regulation at § 413.236(b), we will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired). Specifically, the equipment or supply must represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Under the first criterion, as reflected in the CY 2020 ESRD PPS final rule, renal dialysis equipment and supplies will be considered “new” if FDA grants them marketing authorization on or after January 1, 2020. By including FDA marketing authorizations on or after January 1, 2020, we intended to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. We note in section II.B.2.b of this proposed rule, we are proposing to refine the newness criteria (year in which the product was approved) and establish that an equipment or supply is considered “new” within 3 years beginning on the date of FDA marketing authorization for that equipment or supply. For capital-related assets that are dialysis machines when used in the home setting, the 3

years would begin from the date of FDA marketing authorization for home use.

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

We finalized the adoption of IPPS's SCI criteria specified in § 412.87(b)(1), including modifications finalized in future IPPS final rules, to determine when a new and innovative renal dialysis equipment or supply is eligible for the TPNIES under the ESRD PPS. That is, we would adopt IPPS's SCI criteria in § 412.87(b)(1) and any supporting policy around these criteria as discussed in IPPS preamble language. We stated that we believed that by incorporating the IPPS SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have standard criteria to meet for both settings. We also proposed to establish a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87. That is, we proposed that CMS would use a similar process to determine whether the renal dialysis equipment or

supply meets the eligibility criteria proposed in newly added § 413.236(b). Similar to how we evaluate whether a new renal dialysis drug or biological product is eligible for the TDAPA, as discussed in the CY 2016 ESRD PPS final rule (80 FR 69019), we would need to determine whether the renal dialysis equipment and supply meets our eligibility criteria for the TPNIES.

Specifically, under § 413.236(b)(5) we evaluate SCI for purposes of the TPNIES under the ESRD PPS based on the IPPS SCI criteria (see § 412.87(b)(1)). We note that in section II.B.2.a of this proposed rule we provide a detailed discussion of the SCI criteria. In addition, in section II.B.2.b of this proposed rule we are proposing to revise § 413.236(b)(5) to remove “and related guidance” to reflect that all related SCI guidance has now been incorporated into § 412.87(b)(1).

As we discuss in section II.B.2.a, in the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established in § 413.236(c) a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b). Then, after consideration of public comments we will announce the results in the **Federal Register** as part of our annual ESRD PPS final rule. We noted we would only consider a complete application received by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We note in section II.B.2.b of this proposed rule we are proposing to revise § 413.236(c) to replace “September 1” with “the HCPCS Level II code application deadline for Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website” to reflect that FDA marketing authorization for the new and innovative equipment or supply must accompany

the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year.

2. CY 2021 Applications for the TPNIES

We received two applications for the TPNIES for CY 2021. A discussion of these applications is presented below.

a. Theranova 400 Dialyzer and Theranova 500 Dialyzer

(1) Baxter Healthcare Corporation (Baxter) Application

Baxter submitted an application for the Theranova 400 Dialyzer / Theranova 500 Dialyzer. The 400 and 500 denote differences in surface area. The applicant stated that Theranova represents an SCI over currently available hemodialysis (HD) therapies for the treatment of renal failure. The applicant stated that Theranova is a new class of hollow-fiber, single-use dialyzer intended to treat renal failure by HD. The applicant stated that it features an innovative 3-layer membrane structure that offers a higher permeability than high-flux dialyzers, with improved removal of large proteins up to 45 kilodaltons (kDa) while selectively maintaining essential proteins such as albumin.^{16,17,18} The applicant stated that Theranova has the potential to transform in-center HD by allowing Medicare beneficiaries with renal failure to benefit from expanded hemodialysis (HDx). HDx is defined as a process of blood purification that includes the clearance of small uremic toxins through large middle molecule (LMM) (categorized as uremic solute whose molecular size is 25kDa up to 60 kDa) toxins without the

¹⁶ Boschetti-de-Fierro, A., et al., "MCO Membranes: Enhanced Selectivity in High-Flux Cases," *www.nature.com/Scientific Reports*, [5:18448]DOI: 10.1038/srep18448

¹⁷ Krause, B., et al., "Highly selective membranes for Blood purification," Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015

¹⁸ Zweigart, C., et al., "Medium cut-off membranes – closer to the natural kidney removal function," *Int. J Artif Organs*, 2017, 40(7), pp. 328-334. DOI: 10.5301/ujao.5000603.

need for an external infusion of replacement fluid. For purposes of the application, HDx is collectively referred to in the application as “Theranova”. The applicant asserted that the Theranova dialyzer integrates with existing HD machines that an ESRD facility already owns and replaces other dialyzers.

The applicant described the Theranova membrane as unique and stated it allows for the removal of an expanded range of solutes, creating a filtration profile closer to a natural kidney. The applicant described the membrane structure as being divided into three distinct layers: a fingerlike porous outer layer, a sponge-like intermediate layer, and a very thin inner layer (skin). By reducing the inner diameter of the membrane, internal filtration is increased, allowing for enhanced clearance of LMMs through additional convective transport.¹⁹ The Theranova dialyzer enables the efficient removal of uremic toxins (up to 45 kDa).^{20,21} The applicant included an adapted figure from a book titled, “Modelling and Control of Dialysis Systems²² to compare removal of toxins by Theranova to the kidney and to other dialysis therapies, such as low flux dialyzers (LF), high flux dialyzers (HFD) and hemodiafiltration (HDF). The applicant’s adapted figure showed the following: LF, HFD, HDF and HDx remove urea (60 Daltons (Da)), phosphate (96 Da), Parathyroid hormone (9,500 Da); HFD, HDF and HDx remove Beta 2 microglobulin (12 kDa), cystatin C (13 kDa), Myoglobin (17 kDa), and, kappa free-light-chains (23 kDa); HDF and HDx remove complement factor D (24 kDa), Interleukin (IL)-6 (25

¹⁹ Lorenzin, A., et al., “Quantification of Internal Filtration in Hollow Fiber Hemodialyzers with Medium Cut-Off Membrane,” *Blood Purif*, 2018, 46, pp. 196-204.

²⁰ Boschetti-de-Fierro, A., et al., “MCO Membranes: Enhanced Selectivity in High-Flux Cases,” www.nature.com/Scientific Reports, [5:18448] DOI: 10.1038/srep18448

²¹ Boschetti-de-Fierro, A., et al., “MCO Dialyzers: Enhanced Selectivity High-Flux,” Gambro Dialysatoren GmbH, Research and Development, Hechingen, Germany, Poster No. SAT-481 (Baxter)

²² Azar, A.T. and Canaud, B., “Chapter 8: Hemodialysis System,” *Modeling and Control of Dialysis Systems*, 2013, pp. 99-106, SCI 404 Berlin, Springer-Verlag, Berlin, Heidelberg. ISBN: 978-3642274572.

kDa), alpha 1 microglobulin (33 kDa); and, HDx removes Chitinase-3-like protein 1 (40 kDa), lambda free-light-chains (45 kDa) and albumin (67 kDa).

The applicant stated that compared with low-flux HD, high-flux HD, and HDF, the Theranova dialyzer filtration profile is more similar to that of a natural kidney, as shown *in vitro*^{23,24} giving it expanded clearance of uremic toxins.

The applicant asserted that the design of the Theranova dialyzer allows for use on any HD machine, made by any manufacturer, by merely changing the dialyzer. The applicant stated that the membrane is compatible with standard fluid quality and does not require any additional fluid quality control measure.

Theranova received approval for Investigational Device Exemption (IDE) protocol from the FDA, on August 31, 2017 and then received approval for coverage on September 13, 2017. The Class II investigational device exemption received the code G170157.²⁵ The FDA requested a 6-month clinical study to validate efficacy of large toxin removal and safety. According to the applicant, safety is defined in part by albumin loss. The applicant stated that it is seeking authorization through the FDA's De Novo pathway and marketing authorization this year for the May 2020 cycle. The applicant stated that it plans to submit a HCPCS application to CMS in June 2020.

²³ Krause, B., et al., "Highly selective membranes for Blood purification," Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015

²⁴ Boschetti-de-Fierro, A., et al., "MCO Membranes: Enhanced Selectivity in High-Flux Cases," *www.nature.com/Scientific Reports*, [5:18448] DOI: 10.1038/srep18448

²⁵ Available on p. 49828 at: <https://www.federalregister.gov/documents/2017/10/27/2017-23447/medicare-and-medicaid-programs-quarterly-listing-of-program-issuances-july-through-september-2017>

The applicant noted that it has not submitted an application for pass-through payments under the Medicare Outpatient Prospective Payment System (OPPS) or the NTAP program under the Medicare IPPS for the Theranova 400 Dialyzer / Theranova 500 Dialyzer.

The applicant stated that it expects Theranova to be commercially available immediately after receiving marketing authorization and will provide proof of commercial availability.

With regard to demonstrating the requirements for SCI, the applicant asserted that Theranova represents an SCI in outcomes for Medicare beneficiaries over currently available HD therapies treating renal failure. The applicant noted that ESRD patients on current HD therapies suffer unsatisfactorily high mortality and morbidity from cardiovascular disease and infections.²⁶

In addition, the applicant stated that the HDx enabled by Theranova effectively targets the removal of LMM uremic toxins (25 kDa to 60 kDa), which are linked to the development of inflammation, cardiovascular disease, and other comorbidities in dialysis patients. The applicant stated that this results in improved clinical outcomes, relative to current dialyzers in four clinical categories. First, a decreased rate of subsequent therapeutic interventions, including fewer infections, reduced hospitalization duration, and reduced medication usage. Specifically, the applicant stated that patients treated with HDx therapy have decreased infections. A prospective cross-over study found an average of seven episodes of infection for patients treated with HDx versus 18 for high flux HD (p=0.003).²⁷ The applicant also stated that patients receiving HDx therapy with Theranova had hospital stays averaging 4.4 days versus 5.9 days for patients

²⁶ United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

²⁷ Cozzolino, C., et al., "Effects of a medium cut-off (Theranova) dialyzer on haemodialysis patients: a prospective, cross-over study," *Clinical Kidney Journal*, 2019, pp. 1-8. Doi 10.1093/ckj/sfz 155.

receiving traditional HD ($p=0.0001$) along with lower hospitalization rates (71 percent versus 77 percent ($p=0.69$)).²⁸ The U.S. IDE Randomized Controlled Trial (NCT03257410) of 172 patients, although not powered for all-cause hospitalization events, showed a 49 percent decreased number of hospitalization events in the TheraNova arm (18 events) as compared to the control arm (37 events).²⁹ With regard to improved medication usage, the applicant stated that patients receiving HDx therapy had reduced medication usage. The applicant cited three studies that showed a significant decrease in erythropoietin stimulating agents (ESA) usage.^{30,31,32} One study also found a substantial reduction in the need for iron usage.^{33,34} Two studies saw an improvement in EPO resistance index (ERI) and one study showed a statistically significant decrease in phosphate binder (calcium carbonate) usage.^{35,36}

The second clinical improvement category listed by the applicant is a more rapid beneficial resolution of the disease process treatment. The applicant cited a 2019 publication which noted that the average recovery time after dialysis is reduced with HDx therapy, with the median self-reported recovery time at 120 minutes, 60 min., 60 min., and 105 min. at 3,6,9, and 12 months compared to a baseline 240 min. ($p<0.01$ for 6, 9, and 12-month ratings; $N=110$).³⁷

²⁸ Sanabria, R.M., et al. "Expanded Hemodialysis and its effects on hospitalizations and medication usage," Submitted for publication.

²⁹ Weiner, D.E., et al. 2019, "Efficacy and Safety of Expanded Hemodialysis with the TheraNova 400 Dialyzer: A Randomized Control Trial," Abstract at ASN meeting, FR-PO 488.

³⁰ Gallo, M., "The Real-Life Study on Expanded Hemodialysis (HDx): 9 Months Experience of a Single Hemodialysis Unit," *Nephrology Dialysis Transplantation*, 34, Issue Supplement_1, June 2019, [gfz106.FP539](https://doi.org/10.1093/ndt/gfz106.FP539), <https://doi.org/10.1093/ndt/gfz106.FP539>

³¹ Sanabria, R.M., et al., Ibid.

³² Lim, J-H., et al., "Novel Medium Cut-Off Dialyzer Improves Erythropoietin Stimulating Agent Resistance in Maintenance Hemodialysis Patients: A Randomized Controlled Trial," Manuscript submitted for publication.

³³ Sanabria, R.M., et al., Ibid.

³⁴ Lim, J-H., et al., Ibid.

³⁵ Sanabria, R.M., et al., Ibid.

³⁶ Lim, J-H., et al. Ibid.

³⁷ Bolton, S., et al., "Dialysis symptom burden and recovery time in expanded hemodialysis," Manuscript submitted.

The third category of improved clinical outcomes listed by the applicant is reduced inflammation in patients receiving HDx Therapy with Theranova. The applicant referenced a 2018 review article, which notes that chronic inflammation in ESRD patients is associated with the build-up of known uremic toxins spanning the molecular size spectrum from 12kDa to 45kDa such as beta- 2-microglobulin, soluble tumor necrosis factor (TNF), Receptor 2, IL-1 , Prolactin, IL-18, IL-6, Hyaluronic Acid, TNF-a, Soluble TNF Receptor 1, Pentraxin-3, and Advanced Glycation End-Products. The same article notes the following: 1) LMM (25 kDa to 60 kDa) have been associated with inflammation, cardiovascular events and other dialysis-related comorbidities; 2) current dialytic therapies, though efficient in removing small solutes, have limited capability in removing LMM; 3) current dialyzer design, limited by membrane permeability, does not provide long-lasting, effective reduction of the full spectrum of small molecular uremic toxins (<500 Da), conventional middle molecular uremic toxins (500 Da to <25 kDa) and large middle molecular uremic toxins (25 kDa to 60kDa), even when their usage is enhanced with convective transport; and 4) a broad spectrum of uremic toxins are not effectively treated by conventional HD nor HDF which is not readily utilized in the U.S.³⁸ The applicant asserted that for the first time, HDx enabled by Theranova results in the superior removal of the aggregate of small, conventional middle and large middle molecular uremic toxins.³⁹ The applicant asserted that Theranova, in effectively targeting the spectrum of uremic toxins, that this spectrum encompasses the totality of these inflammation-modulating molecules.

³⁸ Wolley, M., et al., “Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules,” *Clin J Am Soc Nephrol*, 2018, 13, pp.805-813.

³⁹ Kirsch AH, Lyko R, Nilsson LG., et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transplant* 2017; 32: 165–172.

The applicant also asserted that when analyzing the full set of studies utilizing Theranova dialyzers, the collective evidence shows consistent improvement in these inflammatory marker levels. Of 14 measurements of inflammation across four studies,^{40,41,42,43} 71 percent (10 of 14) showed statistically significant improvement in the inflammatory marker. For the remaining 29 percent of the measured inflammatory markers, all showed improvement in the inflammatory profile but were not statistically significant. In most of the situations where statistically significant results were not achieved, the applicant asserted, the studies were underpowered to demonstrate statistically significant change of the particular marker.

The applicant stated that studies have demonstrated stable albumin levels,^{44,45} and a reduction of endothelial dysfunction and Albumin and C-Reactive Protein (CRP) levels.^{46,47,48} In addition, the applicant specifically described a single cohort study (N=41) showing a significant decrease in serum levels for urea, β_2m , kappa and lambda free light chain at 3 months. At 3 and 6 months, there was a substantial decrease in serum CRP levels. Also, blood assay demonstrated a decline in the production of IL-6.⁴⁹ In a 40-participant cross-over prospective study, HDx with

⁴⁰ Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High Flux Dialyzers: A Randomized Clinical Trial," *Nephrol Dial Transplant*, 2020, 35, pp. 328-335.

⁴¹ Kharbanda, K., et al., "A Randomised Study Investigating the Effect of Medium Cut-Off Haemodialysis on Markers of Vascular Health Compared with On-Line Haemodiafiltration (MoDal Study)". Poster presented at the American Society of Nephrology, 2019.

⁴² Cozzolino, M., "Effects of Medium Cut-Off (Theranova) Dialyzer on Hemodialysis Patients: A Prospective Cross-Over Study [Abstract]." *J Am Soc Nephrol*, 29, 2018, pp. 616-617.

⁴³ Cantaluppi, V., et al., "Removal of Large Middle Molecules on Expanded Hemodialysis (HDx): A Multicentric Observational Study of 6 Months Follow-Up," *J Am Soc Nephrol*, 29, 2018, Poster TH-PO 357.

⁴⁴ Krishnasamy, R., et al., "Trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients (REMOVAL-HD): a safety and efficacy study," 2018, ASN 2018 Kidney Week Abstract TH-P0353.

⁴⁵ Bunch, A., et al., "Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients," 2018, ASN 2018 Kidney Week Abstract FR-P0766.

⁴⁶ Kharbanda, k., et al. 2019, Ibid.

⁴⁷ Cantaluppi, V., et al., Ibid.

⁴⁸ Cantaluppi, V., et al., "Removal of Large- Middle Molecules, Inhibition of Neutrophil Activation and Modulation of Inflammation-Related Endothelial Dysfunction During Expanded Hemodialysis (HDx)," June 2019, *Nephrol Dial Transplantation*, 34, Issue Supplement_1. gzf096.FO048, <https://doi.org/10.1093/ndt/gfz096.FO048>.

⁴⁹ Cantaluppi, V., et al., Ibid.

Theranova versus high flux HD demonstrated both a higher reduction ratio and a decrease in serum levels for lambda free light chains.^{50,51,52}

The applicant also noted that, in addition to IL-6, a well-recognized biological marker of inflammation, there is also a broader spectrum of uremic toxins associated with inflammation. The applicant listed references for elevated levels of IL-6 leading to the following: hepcidin production with decreased iron availability;⁵³ increased endothelial damage;^{54,55} increased CRP and decreased albumin production.⁵⁶ The applicant attested that with the use of Theranova, patients present clinically with the opposite of each of the above listed concerns, suggesting that chronic inflammation mediated by IL-6 is reduced by treatment with Theranova. However, the applicant submitted a reference which concluded that when compared to HD using high flux membrane, HD using a medium cut-off (MCO) membrane may be not inferior in albumin loss.⁵⁷

An additional prospective cross-over study (N=20) showed reduced levels of IL-6 (6.4561.57 pg/m vs. 9.4862.15 pg/ml) in patients treated with HDx.⁵⁸ The applicant included findings from their U.S. IDE Study in the TPNIES application. Although the IL-6 level was not

⁵⁰ Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High Flux Dialyzers: A Randomized Clinical Trial," J Am Soc Nephrol, 2018, 29, Poster TH-PO348.

⁵¹ Belmouaz M, et al., "Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle-sized molecules," Clin Nephrol. Jan 2018, 89 (2018)(1):50-56.

⁵² Belmouaz, M., et al., "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial," Nephrol Dial Transplant, 2020, 35, pp. 328-335.

⁵³ Caramelo, C., et al., "Anemia: Pathophysiology, pathogenesis, treatment, incognitate," Rev Esp Cardiol., 2007, 60, pp. 848-60.

⁵⁴ Kharbanda, K., et al., "A randomized study investigating the effect of medium cut off haemodialysis on markers of vascular health compared with on-line hemodiafiltration (MoDal Study)," 2019, Presented at the Scientific Congress American Society of Nephrology, 2019.

⁵⁵ Cozzolino, C., et al., "Effects of a medium cut-off (Theranova) dialyzer on haemodialysis patients: a prospective, cross-over study," *Clinical Kidney Journal*, 2019, pp. 1-8. Doi 10.1093/ckj/sfz 155.

⁵⁶ Gillerot, G., et al. "Genetic and Clinical Factors Influence the Baseline Permeability of the Peritoneal Membrane," *Kidney Int.* 2005, 67, pp. 2477-2487.

⁵⁷ Jung, J.H., et al., "A 6-Month Study on the Efficacy of Hemodialysis Therapy Using Dialyzers with Medium Cut-Off Membranes in Asian Patients with End- Stage Renal Disease," *Nephrol Dial Transplant*, June 2019. 84, Issue Supplement, gfz103.SP487, <https://doi.org/10.1093/ndt/gfz103.SP487>.

⁵⁸ Cozzolino, C., et al., 2019, Ibid.

a primary endpoint of the US IDE Study (NCT03257410), nor was the study sufficiently powered to statistically prove a change in IL-6 level, the analysis of the US IDE Study (NCT03257410), comparing Theranova to HD with Elisio 17H, indicates a trend for difference in the pre- to post-dialysis change in plasma IL-6 level, favoring Theranova ($p=0.07$ and $p=0.08$ at 4 weeks and 24 weeks, respectively). The pre-dialysis level of IL-6 shows a positive trend for Theranova ($p=0.2$).⁵⁹ The applicant stated that the accumulation of IL-6 and lambda free light chains may contribute to the chronic inflammation state of ESRD patients, increasing the risk of chronic vascular disease and bacterial infections, respectively. The applicant noted that the company is exploring options to assess the impact of the reduction of these solutes via HDx in ongoing studies.

Finally, the last category of improved clinical outcomes listed by the applicant is enhanced quality of life across many different measures, including, but not limited to, decreased recovery time, decreased restless leg syndrome, and reduced pruritus. The applicant stated that there was decreased symptom burden, citing a study of patients who switched to HDx with Theranova in a multicenter 6-month observational study (N=992), who had statistically significant improvements in measures of symptoms of kidney disease, effects of kidney disease, and the burden of kidney disease.⁶⁰ The applicant also stated that there was improved reported mental health component and statistically significant reduced Restless Leg Syndrome

⁵⁹ Weiner, D.E., et al., 2019 “Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Control Trial,” Abstract at ASN meeting, FR-PO 488.

⁶⁰ Alarcon, J.C., et al., “Real World Evidence on the Impact of Expanded Hemodialysis (HDx) Therapy on Patient Reported Outcomes (PROs): COREXH Registry,” Manuscript submitted for Publication.

diagnosis.^{61,62,63,64} Regarding improved physical functioning and decreased pruritis, the applicant submitted an article reporting the results of a randomized control trial (N=50), where Theranova resulted in improved results for physical functioning and physical role, and the mean scores of mean pruritus distribution and frequency of scratching during sleep were significantly lower with Theranova.⁶⁵ In another study (single cohort, N=14), Theranova was associated with statistically significant improvement in the physical and mental component quality of life measures.⁶⁶ The applicant also submitted a case report of a HD patient with pruritis who responded to the initiation of HDx using a MCO dialysis membrane.⁶⁷

(2) CMS TPNIES Work Group Analysis

(a) Summary of Current Equipment or Supply by the CMS TPNIES Work Group

The following discussion was part of the content of the CMS TPNIES Work Group evaluative meetings.

Patients with ESRD requiring dialysis are at high risk of mortality due to the presence of uremic toxins.⁶⁸ However, identifying the putative uremic toxin (or toxins) has proven challenging; the European Uremic Toxin Work Group previously identified at least 90

⁶¹ Alarcon, J.C., Manuscript submitted for publication, Ibid.

⁶² Gernone, G., et al., "Mid-term Evaluation of the New Medium Cut-Off Filter (Theranova) on Removal Efficiency and Quality of Life," *Nephrology Dialysis Transplantation*, 2018, ERA EDTA Scientific Congress Abstract, SP 489, doi.10.1093/ndt/gfy104

⁶³ Florens, N and Juillard, L., "Expanded haemodialysis: news from the field," *Nephrol Dial Transplant*, 2018, 33, pp. iii48-iii52.

⁶⁴ Bunch, A., et al. "Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients" ASN 2018 Kidney Week Abstract FR-P0766.

⁶⁵ Lim, J-H., et al. "Novel medium cut off dialyzer improves erythropoietin stimulating agent resistance in maintenance hemodialysis: a randomized controlled trial," Submitted for publication.

⁶⁶ Gernone, G., et al., "Mid-term Evaluation of the New Medium Cut-Off Filter (Theranova) on Removal Efficiency and Quality of Life," *Nephrology Dialysis Transplantation*, 2018, ERA EDTA Scientific Congress Abstract, SP 489, doi.10.1093/ndt/gfy104

⁶⁷ Penny, J., et al. "Pruritus: Is there a salty truth?" Submitted for publication.

⁶⁸ Boschetti-de-Fierro, A., et al., "MCO Membranes: Enhanced Selectivity in High-Flux Cases," *www.nature.com/Scientific Reports*, [5:18448] DOI: 10.1038/srep18448

compounds that are retained in patients undergoing dialysis.⁶⁹ Current HD technology relies on diffusion of toxins across a semi-permeable membrane to allow for the removal of small-sized (<500 Da) water-soluble molecules. While HD is generally able to remove water-soluble small toxins (<500 Da), HD has limited ability to clear protein bound solutes, those that are sequestered, or LMM solutes (>500 Da).^{70,71,72} The accumulation of uremic toxins with higher molecular weight is associated with immunodeficiency, inflammation, protein-wasting, and cardiovascular complications. For instance, solutes such as Beta-2 microglobulin (11.8 kDa)^{73,74} are associated with increased mortality.⁷⁵ Protein-bound solutes such as indoxyl sulfate and p-cresol sulfate also appear to be poorly dialyzable and are associated with the uremic syndrome and cardiovascular disease.⁷⁶

While dialysis can eliminate the immediate risk of death from uremia, it does not replace functioning kidneys. Patients receiving adequate dialysis do not completely recover from the uremic syndrome, indicating that other uremic toxins may not fully be cleared.^{77,78} Compared to

⁶⁹ Vanholder R, et al., European Uremic Toxin Work Group (EUTox). Review on uremic toxins: classification, concentration, and interindividual variability. *Kidney Int*, 2003 May;63 (5):1934-43.

⁷⁰ Macías N., et al., "Middle molecule elimination in expanded haemodialysis: only convective transport" *Clin Kidney J.*, Dec. 2018, 15;12 (3), pp. 447-455.

⁷¹ García-Prieto, A., et al., "Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration." *Clin Kidney J.*, Oct. 2018, 11(5):742-746.

⁷² Dobre, M., et al., "Searching for Uremic Toxins" *Clinical Journal of American Society of Nephrology*. February 2013, 8 (2) 322-327.

⁷³ Belmouaz, M., et al. "Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial," *J Am Soc Nephrol*, 29, 2018, Poster TH-PO348.

⁷⁴ Belmouaz, M., et al., "Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle-sized molecules," *Clin Nephrol*. Jan 2018, 89 (2018)(1):50-56.

⁷⁵ Cordeiro, I., et al." High-Flux versus High-Retention-Onset Membranes: In vivo Small and Middle Molecules Kinetics in Convective Dialysis Modalities," *Blood Purification*, Jul 2019, 30:1-8.

⁷⁶ Vanholder, R., et al., "Protein-bound uremic solutes: The forgotten toxin," *Kidney International*. Feb 2001, 59 (78), S266-S270.

⁷⁷ Tanaka H, Sirich TL, Plummer NS, Weaver DS, Meyer TW. An Enlarged Profile of Uremic Solutes. *PLoS One*. 2015; 10(8): e0135657.

⁷⁸ Sirich, T.L., et al., "The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial." *Kidney Int*, May 2017, 91 (5): 1186–1192.doi:10.1016/j.kint.2016.11.002.Epub 2017 Jan 12.

the general population, patients with ESRD who receive dialysis are at an increased risk of death, commonly suffer from uremic symptoms such as itching, restless legs, and malnutrition, and are at increased infection risk. Conventional dialysis is effective in removing small molecules, but is less effective in removing larger molecules, sequestered molecules, and protein-bound toxins. Accumulation of middle molecule and protein-bound toxins may contribute to adverse outcomes among patients receiving dialysis⁷⁹ and may explain why even a small amount of “residual” kidney function is strongly associated with increased survival^{80,81} and higher quality of life.^{82,83}

Innovations in dialysis care include the development of technologies that might remove potential toxins resistant to clearance using current devices. One technology called HDF removes larger molecules by combining convection with diffusion. Convection relies on pressure gradients across the dialyzer membrane, leading to more effective removal of middle to large molecules from the blood. Substantial fluid losses with convection, must be replaced via infusion of typically ultrapure water and dialysis fluids.⁸⁴ This newer technology was later supplemented by online HDF, which enables dialysis providers with ultrapure water systems to generate replacement fluid solution. Although HDF has been associated with improvements to

⁷⁹ Clark, W.R., et al. “Uremic Toxins and their Relation to Dialysis Efficacy.” *Blood Purif.*, 2019,48(4), pp.299-314. Epub 2019 Sep 27.

⁸⁰ Obi, Y., et al., “Residual Kidney Function Decline and Mortality in Incident Hemodialysis Patients,” *J Am Soc Nephrol.*, Dec. 2016, 27(12), pp. 3758-3768. Epub 2016 May 11.

⁸¹ Wang, A.Y. and Lai, K.N. “The importance of residual renal function in dialysis patients.” *Kidney Int.*, May, 2006, 69(10), pp. 1726-32.

⁸² Dobre, M., et al., “Searching for Uremic Toxins” *Clinical Journal of American Society of Nephrology*. February 2013, 8 (2) 322-327.

⁸³ Bargman, J.M., et al., “CANUSA Peritoneal Dialysis Study Group. Relative contribution of residual renal function and peritoneal clearance to adequacy of dialysis: a reanalysis of the CANUSA Study,” *J Am Soc Nephrol.*, Oct. 2001, 12(10), pp. 2158-62.

⁸⁴ Zweigart, C., et al., “Medium cut-off membranes – closer to the natural kidney removal function,” *Int. J Artif Organs*, 2017, 40(7), pp. 328-334. DOI: 10.5301/ujao.5000603.

survival in retrospective, observational studies,⁸⁵ randomized controlled trials have been less consistent.^{86,87,88,89} Online HDF has become more widely used in Europe, but it not commonly used in the U.S. due to costs associated with the need for ultrapure water.⁹⁰

Newer dialysis membranes aimed at improved middle molecule clearance are an active area of research.⁹¹ High flux membranes with larger pore sizes can remove larger molecules, including inflammatory cytokines and immunoglobulin light chains but at the cost of albumin loss.⁹² This is significant because low albumin levels are associated with higher mortality rates in patients with ESRD.⁹³

In addition to potential risks associated with efforts to remove larger molecules during dialysis (such as the loss of albumin and immunoglobulins), benefits of improved middle molecule clearance have not been demonstrated in large, randomized-controlled trials. In 2002, a large multicenter randomized controlled trial (HEMO) compared patients receiving maintenance dialysis via high-flux versus low-flux dialyzer membranes. There was no difference in the primary endpoint (death from all causes) or in secondary endpoints

⁸⁵ García-Prieto, A., et al., “Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration.” *Clin Kidney J.*, Oct. 2018, 11(5):742-746.

⁸⁶ Grooteman, M.P., et al.; “CONTRAST Investigators. Effect of online hemodiafiltration on all-cause mortality and cardiovascular outcomes,” *J Am Soc Nephrol.*, June 2012, 23(6), pp.1087-1096.

⁸⁷ Maduell, F., et al., “ESHOL Study Group. High-efficiency postdilution online hemodiafiltration reduces all-cause mortality in hemodialysis patients” *J Am Soc Nephrol.*, Feb 2013, 24(3), pp. 487-497. doi: 10.1681/ASN.2012080875. Epub 2013 Feb 14. Erratum in: *J Am Soc Nephrol.* 2014 May; 25(5):1130.

⁸⁸ Morena, M., et al., “FRENCHIE Study Investigators. Treatment tolerance and patient-reported outcomes favor online hemodiafiltration compared to high-flux hemodialysis in the elderly,” *Kidney Int.*, June 2017, 91(6):1495-1509.

⁸⁹ Ok, E., et al., “Online Haemodiafiltration Study. Mortality and cardiovascular events in online haemodiafiltration (OL-HDF) compared with high-flux dialysis: results from the Turkish OL-HDF Study,” *Nephrol Dial Transplant*, Jan 2013, 28(1), pp. 192-202.

⁹⁰ Zweigart, C., 2017. Ibid

⁹¹ Zweigart, C., 2017. Ibid

⁹² Krause, B., et al., “Highly selective membranes for Blood purification,” Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015

⁹³ Zweigart, C., et al., “Medium cut-off membranes – closer to the natural kidney removal function,” *Int. J Artif Organs*, 2017, 40(7), pp. 328-334. DOI: 10.5301/ujao.5000603.

(hospitalizations for cardiac cause or death, and hospitalizations for infection or death) between the two groups. In rhabdomyolysis, myoglobin clearance has been demonstrated with large pore dialyzers and HDF, but clinical benefit remains largely unproven.⁹⁴ Similarly, HDF has historically garnered much attention in sepsis due to its ability to efficiently clear inflammatory cytokines like IL-6, but numerous studies have shown no mortality benefit in sepsis with possible downsides in the form of shortened filter life.⁹⁵ No trials have examined the potential benefit of removing larger quantities of middle molecules than is typically achieved from high-flux membranes.

The clearance of protein-bound and sequestered molecules remains a technical challenge and may explain why HDF and other technologies aimed at improved middle-molecule clearance have not significantly changed clinical outcomes.⁹⁶ Theoretically, intensive long-duration dialysis should improve the clearance of these difficult to remove substances.⁹⁷ In practice, large randomized trials have not shown any difference in the level of substances like indoxyl sulfate and p-cresol sulfate.^{98,99} Improving clearance of these molecules could improve clinical outcomes in patients without residual renal function and would be a boon to the dismal outcomes faced by patients undergoing dialysis.

⁹⁴ Amyot, S.L., et al., "Myoglobin clearance and removal during continuous venovenous hemofiltration," *Intensive Care Medicine*, 1999 (25), PP. 1169-1172.

⁹⁵ Friedrich J.O., et al., "Hemofiltration compared to hemodialysis for acute kidney injury: systematic review and meta-analysis," *Critical Care*, Aug 6, 2012 (16): R146.

⁹⁶ Vanholder, R., et al., "Protein-bound uremic solutes: The forgotten toxin," *Kidney International*. Feb 2001, 59 (78), S266-S270.

⁹⁷ Sirich, T.L., et al., "The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial." *Kidney Int*, May 2017, 91 (5): 1186–1192.doi:10.1016/j.kint.2016.11.002. Epub 2017 Jan 12.

⁹⁸ Kalim, S., et al., "Extended Duration Nocturnal Hemodialysis and Changes in Plasma Metabolite Profiles," *Clin J Am Soc Nephrol*, Mar 7, 2018, 13(3), pp.436-444.

⁹⁹ Sirich, T.L., et al., "The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial." *Kidney Int*, May 2017, 91 (5): 1186–1192.doi:10.1016/j.kint.2016.11.002.Epub 2017 Jan 12.

(b) Assessment of Substantial Similarity to Currently Available Equipment or Supplies

With regard to the criterion as to whether Theranova uses the same or a similar mechanism of action to achieve a therapeutic outcome, the CMS TPNIES Work Group believes that this product slightly modifies existing HD technology. A MCO membrane was designed for use in HD (but not HFD or HDF) modes. These modifications include the removal of larger molecules and increased convection compared to existing HD. As to whether the new use of the technology involves treatment of the same or similar type of disease and the same or similar patient population, the CMS TPNIES Work Group notes that Theranova treats similar patients, specifically, patients with ESRD.

(c) Preliminary Assessment of SCI (see §§ 413.236(b)(5) and 412.87(b)(1))

With regard to the SCI criteria, we note that Theranova is a treatment modality and does not offer the ability to diagnose a medical condition as discussed in § 412.87(b)(1)(ii)(B). We note that Theranova does not offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The patients who are eligible for this treatment would also be eligible for HD, HDF, or online HDF. The CMS TPNIES Work Group carefully analyzed the evidence submitted as to whether Theranova significantly improves the treatment and clinical outcomes of Medicare beneficiaries relative to renal dialysis services previously available as demonstrated by the totality of the circumstances. Below, we have summarized the clinical evidence for claims of SCI, along with the references submitted by the applicant.

There is significant literature on the topic of MCO membranes and high retention onset dialyzers. To evaluate this specific technology, the CMS TPNIES Work Group performed a literature search for published articles using the Theranova dialyzer and reviewed all articles submitted by the applicant. They are categorized according to an estimated degree of peer

review. Summaries are also provided beneath each citation with disclosures also noted. On the studies with more clinically significant measures, there is more annotation added.

(d) Clinical Evidence for Claims of SCI

Below is a list of references for SCI based on evidence beginning with the highest form of evidence, peer-reviewed journals. We summarize the studies grouped by listings with the most rigorous review to those with the least rigorous review, specifically, those published in Peer-Reviewed Journals, then Review Articles and Editorials, to Posters and Abstracts, including submitted manuscripts, and ending with Incomplete Manuscripts.

Published in Peer-Reviewed Journals

- Belmouaz M, et al.¹⁰⁰ is a retrospective analysis of 10 patients treated with online HDF and then switched to MCO dialysis over 1 year. The authors evaluated three dialysis sessions per patient and noted that there were not significant differences between the two methods in clearance of urea, creatinine, β 2-microglobulin, and myoglobin. The authors received funding support by Baxter.

- Belmouaz M, et al.¹⁰¹ is a cross-over prospective study performed in France. It included 40 patients randomly assigned to receive either 3 months of medium cut-off hemodialysis (MCO-HD) followed by 3 months of high-flux HD (HF-HD), or vice versa. The primary endpoint was myoglobin reduction ratio (RR) after 3 months of MCO-HD. Secondary endpoints were the effect of MCO-HD on other middle-weight toxins and protein-bound toxins,

¹⁰⁰ Belmouaz M, Diomez J, Bauwens M, Duthe F, Ecotiere L, Desport E, Bridoux F. Comparison of hemodialysis with medium cut-off dialyzer and online HDF on the removal of small and middle-sized molecules. Clin Nephrol. 2018 Jan;89 (2018)(1):50-56.

¹⁰¹ Belmouaz M, Bauwens M, Hauet T, Bossard V, Jamet P, Joly F, Chikhi E, Joffrion S, Gand E, Bridoux F. Comparison of the removal of uremic toxins with medium cut-off and high-flux dialysers: a randomized clinical trial. Nephrol Dial Transplant. 2020;35:328-335.

and on parameters of nutrition, inflammation, anemia, and oxidative stress. Compared with HF-HD, MCO-HD provides higher myoglobin and other middle molecules RR and is associated with moderate hypoalbuminemia. The authors noted that the potential benefits of this strategy on long-term clinical outcomes deserve further evaluation. This study was supported by Baxter.

- Boschetti-de-Fierro A, et al.¹⁰² is a report on in vitro testing of four prototypes for MCO membranes as compared to high-flux, high cut-off membranes, and a rat glomerular membrane model. Sieving characteristics were evaluated before and after blood contact. Authors note that increasing pore sizes often results in loss of albumin but controlling the pore size diameter and variance results in enhanced selection for middle sized proteins. A protein layer also forms along the synthetic membrane, further restricting the loss of albumin. All authors were employed by Gambro Dialysatoren, which is part of Baxter International Inc.

- Cordeiro ISF, et al.¹⁰³ is a prospective crossover trial of 16 patients undergoing HF-HD and switched to online hemodiafiltration (oHDF) and high retention onset (HRO) HD for 4 weeks. Molarity concentrations were lowered to greater extent in oHDF and HRO-HD.

- Cozzolino M, et al.¹⁰⁴ is an Italian prospective, open-label, cross-over study in 20 patients which compared the Theranova 400 HDx membrane to conventional HD, showing a non-significant trend of lower IL-1B and IL-6 levels with HDx. Although infections were statistically more likely in the HD population, the definition of infection was vague, and most of them appeared to be with respiratory tract and fever of unknown origin. Because culture

¹⁰² Boschetti-de-Fierro A, Voigt M, Storr M, Krause B. MCO Membranes: Enhanced Selectivity in High-Flux Class. *Sci. Rep.* 5, 18448; doi: 10.1038/srep18448 (2015).

¹⁰³ Cordeiro ISF, Cordeiro L, Wagner CS, et al. High-Flux versus High-Retention-Onset Membranes: In vivo Small and Middle Molecules Kinetics in Convective Dialysis Modalities. *Blood Purification.* 2019 Jul 30:1-8.

¹⁰⁴Cozzolino M, Magagnoli L, Ciceri P, Conte F, Galassi A. Effects of a medium cut-off (Theranova) dialyser on haemodialysis patients: a prospective, cross-over study. *Clinical Kidney Journal,* 2019, 1-8.

evidence was not required, the risk of bias in the categorization of infection is high (for example, upper respiratory tract infections inappropriately treated with antibiotics). The HDx had a non-significant trend towards fewer hospitalizations. Potential risks from HDx include an allergic reaction to polysulphone and lower serum albumin levels. The small sample size, single center disease, and short follow-up mean that the results, while promising, require substantial corroborating evidence in the form of a multi-center, blinded randomized controlled trial. The study was supported by an unrestricted grant from Baxter.

- García-Prieto A, et al.¹⁰⁵ is a crossover study of 18 HD patients who received online HDF for one week, then conventional HD the second week, and the use of a MCO membrane for the third week. Authors collected RR and albumin losses and noted that MCO membranes were similar in efficacy as olHDF. Both online and MCO methods had greater reduction of middle molecules. The study was conducted in Spain and authors did not declare any conflicts of interest.

- Gillerot G, et al.¹⁰⁶ is a research paper submitted by the applicant in which the investigators tested the role of IL-6 gene expression on 156 peritoneal dialysis (PD) patients and its putative role in inflammation. They tested a homogeneous population of 152 from Belgium and the North of France. The investigators believe their findings substantiate the critical role played by IL-6 in the peritoneal membrane and support the hypothesis that underlying mechanisms (regulation of IL-6 gene expression) could regulate systemic and local inflammation

¹⁰⁵ García-Prieto A, Vega A, Linares T, Abad S, Macías N, Aragoncillo I, Torres E, Hernández A, Barbieri D, Luño J. Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration. *Clin Kidney J.* 2018 Oct;11(5):742-746.

¹⁰⁶ Gillerot G, Goffin E, Michel C, Evenepoel P, Van Biesen W, Tintillier M, Stenvinkel P, Heimbürger O, Lindholm B, Nordfors L, Robert A, Devuyst O. Genetic and Clinical Factors Influence the Baseline Permeability of the Peritoneal Membrane. *Kid Int.* 2005; 76: 2477-2487.

in association with comorbidity and uremia. However, they note that confirmation of this hypothesis will require well-designed, adequately powered studies, in different populations and different settings. This study was focused on PD and the Theranova membrane is used in HD, so extrapolation of the IL-6 data to that modality is questionable. These studies were supported by Baxter Belgium.

- Lorenzin A, et al.¹⁰⁷ is a performed mathematical modeling, and through it, the authors calculated that the HRO membranes allowed for internal filtration and high convective volumes.

- Lorenzin A, et al.¹⁰⁸ is a paper in which the authors used semi-empirical methods to estimate convective volumes for Theranova 400 and Theranova 500 under standard 4-hour HD conditions. Using their “most complex” mathematical model that incorporated gradients and blood changes along the dialyzer length, authors estimated internal filtration rates of 300ml/min and 400 ml/min for both hemodialyzers.

- Lorenzin A, et al.¹⁰⁹ is an *in vitro* test of Theranova 400 and 500 at zero net ultrafiltration. Albumin macro-aggregates were labeled with Technetium-99m (99mTc) to assess cross filtration through the length of the filter. Using a gamma camera, local cross filtration and internal filtration were calculated. Authors noted that the MCO membrane allowed for clearance of medium-large molecular weight solutes (~11 KDa) and retention of more albumin without requiring special equipment. The authors had no disclosures.

¹⁰⁷ Lorenzin A, Neri M, Clark WR, et al. Ronco C (ed): Expanded Hemodialysis – Innovative Clinical Approach in Dialysis. Contrib Nephrol. Basel, Karger, 2017, vol 191, pp 127–141.

¹⁰⁸ Lorenzin A, Neri M, Clark WR, Garzotto F, Brendolan A, Nalesso F, Marchionna N, Zanella M, Sartori M, Fiore GB, Ronco C. Modeling of Internal Filtration in Theranova Hemodialyzers. Contrib Nephrol. 2017;191:127-141.

¹⁰⁹ Lorenzin A, Neri M, Lupi A, Todesco M, Santimaria M, Alghisi A, Brendolan A, Ronco C. Quantification of Internal Filtration in Hollow Fiber Hemodialyzers with Medium Cut-Off Membrane. Blood Purif. 2018;46(3):196-204.

- Macías N, et al.¹¹⁰ is a prospective study of 14 patients on maintenance oHDF.

Patients underwent a midweek dialysis session with the Theranova-500 machine under their usual dialysis conditions. Researchers measured the presence of uremic toxins at various molecular weights pre-dialysis, and post-dialysis. Pressures at the inlet and outlet of dialyzer compartments were also measured to estimate direct filtration and back filtration volumes. Researchers used semi-empirical methods to determine that diffusive clearance was more prominent than convective transport (which requires higher volumes). No funding or financial contribution was supplied. Membranes, monitors, and laboratory tests were those routinely used in the dialysis unit.

- Reque J, et al.¹¹¹ is a prospective study of eight patients who either underwent oHDF or underwent HDx with Theranova 500 for 24 sessions. After a 1-week washout with HF-HD, all patients crossed over to the alternative method. Laboratory values were obtained before and after each session, specifically of urea, creatinine, phosphorous, beta2-microglobulin, myoglobin, and prolactin. The urea and beta2-microglobulin reduction ratios were the same but HDx demonstrated higher RR of myoglobin (60 percent compared to 35 percent in HDF). The authors had no disclosures.

Review Articles / Editorials

This is the second grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the studies the applicant provided as follows:

¹¹⁰ Macías N, Vega A, Abad S, Aragoncillo I, García-Prieto AM, Santos A, Torres E, Luño J. Middle molecule elimination in expanded haemodialysis: only convective transport? Clin Kidney J. 2018 Dec 15;12(3):447-455.

¹¹¹ Reque J, Pérez Alba A, Panizo N, Sánchez-Canel JJ, Pascual MJ, Pons Prades R. Is Expanded Hemodialysis an Option to Online Hemodiafiltration for Small- and Middle-Sized Molecules Clearance? Blood Purif. 2019;47(1-3):126-131.

- Caramelo C, et al.¹¹² is an article that reviews the clinical and pathophysiological characteristics of anemia in this context. Particular emphasis has been placed on cellular and molecular regulatory mechanisms, and their implications for treatment. The applicant referenced the review article's language on hepcidin, because it is considered the homeostatic regulator of iron in its intestinal absorption, its recycling by macrophages and its mobilization from liver stores. Its transcription is markedly induced in inflammatory processes, especially by cytokines like IL-6.

- Florens N, et al.¹¹³ is a review article included by the applicant in their application. It summarizes feedback from the first routine use of HDx therapy under real-life conditions in European facilities. The authors reported no adverse event after 5,191 HDx treatments, and opined that patients suffering from itching, restless legs syndrome, persistent asthenia or malnourishment could benefit from HDx therapy. While they discuss here the promising applications in which HDx could be valuable (myeloma, rhabdomyolysis or cardiovascular diseases), the message is mitigated by reminding why and how prudence should be taken in the design of future HDx studies, particularly with poor de-aeration of the filter in automatic mode and manual intervention required to prime the membrane. Some patients requiring more anti-coagulation using the Theranova membrane, and patients being aware of the use of the Theranova device because of lack of logo removal. The authors note that although promising, the clinical evidence is incomplete. Both authors received a grant Investigator Initiated research for the evaluation of HDx in clinical practice and one performed occasional lectures for Baxter.

¹¹² Caramelo C, Just S, Gil P. Anemia in Heart Failure: Pathophysiology, Pathogenesis, Treatment and Incognitae. *Rev Esp Cardiol.* 2007; 60(8): 848-860.

¹¹³ Florens N, Juillard L. "Expanded Haemodialysis: News from the Field," *Nephrol Dial Transplant*, 2018; 33: iii48-iii52.

- Wolley M, et al.¹¹⁴ is a clinical review article that recognizes that advances in dialysis technology do not always improve patient outcomes, and it reviews the clinical relevance regarding the removal of LMMS, particularly those involved in chronic inflammation, atherosclerosis, structural heart disease, and secondary immunodeficiency. The authors note that single-center safety and efficacy studies have identified that use of these membranes in maintenance dialysis populations is associated with limited loss of albumin and increased clearance of large middle molecules. When the review was published in 2018, the authors noted that larger, robustly conducted, multicenter studies were evaluating these findings. They concluded that after completion of these safety and efficacy studies, the perceived clinical benefits of providing clearance of LMMS must be assessed in rigorously conducted, randomized clinical studies. One of the authors received research funding from Baxter and participated on advisory boards and speaker bureaus for Baxter.

- Zweigart C, et al.¹¹⁵ is an editorial review submitted by the applicant on MCOs, which was generally favorable with regard to high quality and good performance. All of the authors are employees of the Gambro Dialysatoren GmbH, Hechingen (Germany) or Gambro Lundia AG. Gambro AB (including all direct and indirect subsidiaries) is now part of Baxter International Inc.

Posters and Abstracts

This is the third grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the poster sessions and abstracts, including submitted manuscripts

¹¹⁴ Wolley M, Jardin M, Hutchinson, C. “Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules,” *Cli, J Am Soc Nephrol* 2018;13: 805-813.

¹¹⁵ Zweigart C, Boschetti-de-Fierro A, Hulko M, Nilsson L-G, Beck W, Storr M, Krause B. Medium Cut-Off Membranes – Closer to the Natural Kidney Removal Function. *Int j Artif Organs*. 2017; 40(7); 328-334.

which the applicant provided as follows:

- Belmouaz M, et al.¹¹⁶ is a randomized open label crossover study in which 46 patients underwent MCO-HD and HF-H). MCO-HD had higher medium RRs of myoglobin and beta-2 microglobulin and increased albumin loss compared to HF-HD. The authors received funding support by Baxter.

- Boschetti-de-Fierro A, et al.¹¹⁷ is a poster in which the investigators assessed the performance of the MCO devices in simulated HD and HDF treatments. The applicant's submission of the material presented in this poster was incomplete regarding date and location of the poster session. This study was funded by Baxter.

- Kharbanda K, et al.¹¹⁸ is a randomized study funded by Baxter Healthcare and the National Institute for Health Research which compared HDF with HDx and suggested an improved recovery time with HDx. The study showed lower levels of endothelial cell microvesicles in HDx. However, the study did not have comparable baseline recovery times (for example, 41 percent with < 2 hours with HDx versus 35 percent with HDF) and the authors performed a per-protocol rather than an intention to treat analysis, exacerbating bias in the study.

- Kirsch AH, et al.¹¹⁹ is a poster that summarizes a two pilot randomized controlled prospective open-label crossover studies, in which 39 HD patients underwent treatment with MCO membranes, a HFD, and HDF. Authors concluded that MCO-HD removed middle

¹¹⁶ Belmouaz M, Bauwens M, Bouteau I, Thierry A, Ecotiere L, Bridoux F. Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial. TH-PO348, 2018.

¹¹⁷ Boschetti-de-Fierro A, Voigt M, Huiko M, Krause B. MCO Dialyzers: Enhanced Selectivity in High-Flux. Gambro Dialysatoren GmbH, Research and Development, Hechingen, Germany, Poster No. SAT-481 (Baxter).

¹¹⁸ Kharbanda K, Herring A, Wilkinson F, Alexander Y, Mitra S. A Randomised Study Investigating the Effect of Medium Cut-Off Haemodialysis on Markers of Vascular Health Compared with On-Line Haemodiafiltration (MoDal Study). Manchester Metropolitan University. 2019

¹¹⁹ Kirsch AH, Lyko R, Nilsson LG., et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transplant* 2017; 32: 165–172.

molecules (free light chain) more effectively than high-flux and high-volume HDF. However, the authors noted that there are several limitations of the study. First, compared to the control dialyzers used, the experimental membranes used were different, less tight membranes. Second, the study design was confined to only one single treatment with each dialyzer for each patient and the study did not examine the long term effects of such membranes on serum levels of middle molecules and albumin. The authors conclude that future studies should assess whether the performance of MCO-HD improves clinical outcomes. The study was conducted in Germany and funded by Baxter, and the conflicts of interest statement in the paper lists three of the ten authors as employees of Baxter.

- Bunch, A, et al.¹²⁰ is a multicenter prospective study in prevalent HD patients, older than 18 years old; enrolled from September 1 to November 30, 2017, and converted to HDx using Theranova 400. The investigators found an initial small decrease in serum albumin level, which stabilized and was within the normal range per their Bogota, Columbia laboratory references. Although Table 1 and Table 2 were cited in the abstract, both were missing. Dialysis performance adequacy (Kt/V) was achieved. No clinically significant differences in laboratory values at 6 months with November 30 of 2017, and converted to HDx using Theranova 400 (3 sessions per week, 4 hours per session, same heparin dose). The lead author has been listed as the medical director of Renal Therapy Services, owned by Baxter, in Bogota, Columbia.

¹²⁰Bunch A., Nilsson L, Vesga J, Ardila F, Zuniga E, Alarcon J. “Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients” ASN 2018 Kidney Week Abstract FR-P0766.

- Cantaluppi V, et al.¹²¹ is a multicentric observational study of 6 months follow-up.

American Society of Nephrology (ASN) Week, 2018, Abstract, Thu-PO357. This multicenter (Italy) study evaluated 41 HD patients comparing standard HD molecular levels versus HDx and found a significant decrease in urea, beta-2-microglobulin, and free light chains. The study did not evaluate clinical outcomes.

- Cantaluppi V, et al.¹²² is an abstract submitted by the applicant reporting on a study where 41 HD patients (age 67,6±13,4) in standard high flux HD were shifted to HDx using Theranova 400 (1.7 m², Baxter). Each patient was studied at baseline HD (T0), 3 months (T3) and 6 months (T6) after HDx, after which they were evaluated the following pre-dialysis parameters: Urea, Creatinine, Phosphate, Beta2-microglobulin, Myoglobin, Free Light Chains, Hemoglobin, Albumin and CRP. For in vitro studies, T0 and T6 plasma were used to evaluate neutrophil activation (ROS generation, apoptosis, adhesion) and endothelial dysfunction/senescence. The investigators concluded that HDx therapy provided high removal of different LMMs, leading to a significant reduction of molecules involved in uremia-associated inflammation and organ dysfunction (in particular Free Light Chains kappa and lambda). Long-term studies with a larger sample size are needed to evaluate the clinical impact of HDx.

- Cozzolino, M.¹²³ is an abstract of a pilot study with 20 prevalent HD patients studied for six months in two dialysis treatments: one MCO (Theranova) dialyzer and one high-flux

¹²¹ Cantaluppi V, Donati G, Lacquaniti A, Cosa F, Gernone G, Marengo M, Teatii U Removal of large-middle molecules on expanded hemodialysis (HDx): a multicentric observational study of 6 months follow-up. ASN Week, 2018, Abstract, Thu-PO357.

¹²² Cantaluppi V, Marengo M, Alessandro Q, Berto M, Donati G, Antonio L, Cosa F, Gernone G, Teatini U, Migliori M, Panichi V. Removal of Large-Middle Molecules, Inhibition of Neutrophil Activation and Modulation of Inflammation-Related Endothelial Dysfunction During Expanded Hemodialysis (HDx), *Nephrol Dial Transplantation*, June 2019, 34, Issue Supplement_1. gzf096.FO048, <https://doi.org/10.1093/ndt/gfz096.FO048>

¹²³ “Effects of Medium Cut-Off (Theranova) Dialyzer on Hemodialysis Patients: A Prospective Cross-Over Study [Abstract].” *J Am Soc Nephrol*, 29. 2018, pp. 616-617.

dialyzer. The author claims the pilot study shows the Theranova dialyzer has a good tolerance profile and reduces the cumulative number of infections in HD patients. The study was funded by an unrestricted grant from Baxter.

- Gallo M.¹²⁴ is a single cohort study in Italy which compared HDx to baseline HD treatments in 15 patients and showed no difference in uremic toxins, though there was a change in ESA dose.

- Gernone G, et al.¹²⁵ is a single cohort study in Italy which investigated 14 patients using Theranova with baseline HD and showed no statistical change in outcomes, clearance, or quality of life.

- Jung JH, et al.¹²⁶ is a study that was questionably designed since they chose young, well-nourished patients at the start of the study, which made it difficult to analyze the comparison of the two groups at various points in time. This observational study of 42 Korean patients comparing HD to HDx showed no comparative difference between the two groups in any markers.

- Krishnasamy R, and Hutchinson C.¹²⁷ is an abstract submitted by the applicant from this single-arm, multi-center study with 92 Australian / New Zealand patients. The study examined the safety and efficacy and patient-centered outcomes of MCO dialyzer use in chronic

¹²⁴ Gallo M. The Real-Life study on expanded hemodialysis (HDx): 9 months experience of a single hemodialysis unit. *Nephrol Dial Transplantation and Transplantation*, June 2019, ERA EDTA Abstract. FP539.

¹²⁵ Gernone G, Montemurro M, Capurso D, Colucci G., Dell'Anna D, Deltomaso F, LaRosa R, La Volpe M, Partipilo F., Pepe V, Ripa E. Mid-term evaluation of the new medium cut-off filter (Theranova) on removal efficiency and quality of life. *Nephrology and Transplantation*, Abstract. SP489.

¹²⁶ Jung JH, Song JH, Ahn S-H. A 6-month study on the efficacy of hemodialysis therapy using dialyzers with medium cut-off membranes in Asian patients with end-stage renal disease. *Nephrol Dial Transplantation*, June 2019, 84 Issues Supplement-1, gfz103.SP487, <https://doi.org/10.1093/ndt/gfz103.SP487>.

¹²⁷ Krishnasamy R, and Hutchinson C. Trial Evaluating Mid Cut-Off Value Membrane Clearance of Albumin and Light Chains in Hemodialysis Patients (REMOVAL-HD): A Safety and Efficacy Study. Oct. 2018 ASN Scientific Congress Abstract TH-PO363.

HD patients over 6 months. The investigators concluded that there was a small but acceptable reduction in serum albumin in regular HD using the MCO dialyzer. However, the figures were not included in the abstract sent by the applicant for review by the CMS TPNIES Work Group. The investigator noted that future randomized controlled trials should assess the impact of the MCO dialyzer on clinical and long-term patient-centered outcomes.

- Krause B, et al.¹²⁸ is a description of membrane manufacturing utilizing hollow fiber technology.

- Weiner DE, et al.¹²⁹ included two items for this U.S. based study at a large academic medical center. The first was the ASN 2019 Scientific Congress abstract and the second was a copy of the poster session at the ASN annual meeting in 2019. This open label randomized controlled trial in 172 patients who underwent 24 weeks of Theranova 400 MCO dialyzer compared to a high flux dialyzer showed a potential decrease in hospitalizations with HDx, but the authors did not produce statistical tests of significance. While this was a randomized control trial (RCT), covariates were not well-balanced, including substantially more patients with diabetes in the conventional HD arm. The study showed lower lambda free light chains in HDx compared to high flux HD. Albumin levels were maintained in both. The presenters concluded that larger studies of longer duration are needed to assess if better larger molecule clearance is associated with improvements in clinical outcomes, including vascular disease, quality of life, and mortality. The authors received commercial support from Baxter.

¹²⁸Krause B, Boschetti-de-Fierro A, Dutczak S, Zweigart C. Highly Selective Membranes for Blood Purification. Jahrestreffen der Fachgruppen "Fluidverfahrenstechnik" und "Membrantechnik" 26 Mar 2015.

¹²⁹Weiner DE, Falzon L, Beck W, Xiao M, Tran H, Bernardo AA. Efficacy and Safety of Expanded Hemodialysis Enabled by a Medium Cut-Off Membrane: A Randomized Control Trial. FR-PO488, ASN 2019

- Alarcon J, et al.¹³⁰ describes a study over 12 months in which 992 patients from 12 renal clinics were followed after switching from high-flux HD to HDx. The authors assessed many patient quality of life outcomes using the short form kidney disease quality of life (KDQoL-SF36), dialysis symptom index (DSI) and prevalence of restless leg syndrome (RLS) and found modest reductions in DSI severity scores, increases in KDQoL-SF36 scores in some domains (but unchanged in the mental and physical domains), and reduced prevalence of restless leg syndrome. Unfortunately, the authors did not provide a control group. Also, the authors performed a large number of statistical tests without adjustment, further increasing the risk of Type 1 error. The study was supported by Renal Therapy Services-Columbia, owned by Baxter. Five of the eight authors are employees of Renal Therapy Services. One author is a full-time employee of Baxter and has a patent pending for RLS medication.

- Ariza J, et al.¹³¹ is a manuscript that was provided by the applicant. Cost estimates were extrapolated using an observational design, which suggested lower hospital days (but not hospitalizations) and lower medication use in the HDx. However, the lack of randomization makes this study difficult to evaluate. Furthermore, the authors did not show any difference in costs between HDx and HD. The study was funded by Baxter.

- Penny JD, et al.¹³² is a manuscript in submission that was included by the applicant. It is a single case-study of a HD patient with pruritis and extreme levels of tissue sodium. Both

¹³⁰ Alarcon J, Bunch A, Ardila F, Zuniga E, Vesga J, Rivera A, Sanchez R, Sanabria M. Real world evidence on the impact of expanded hemodialysis (HDx) therapy on Patient Reported Outcomes (PROs): CPREXH Registry (in submission).

¹³¹ Ariza J., Walton SM, Sanabria M, Vega J, Suarez A, Rivera A. An Initial Evaluation of the Potential Cost Impact and Cost Effectiveness of Expanded Hemodialysis (in submission).

¹³² Penny JD, Salerno F, Akbari A, McIntyre, C. "Pruritis-Is There a Salty Truth?" (in submission). The applicant included a manuscript in submission.

responded to HDx therapy. The authors acknowledge that further robust clinical exploration is required.

- Sanabria RM, et al.¹³³ is manuscript provided by the applicant and has not been published. The observational study followed 81 patients receiving high-flux HD for 1 year who subsequently switched to HDx for 1 year. While there was a significant reduction in number of hospital days (but no change in hospitalization rate) and medication use, findings were limited by the lack of a control group. The shortening of hospital stays could be attributed to a systematic change in admission practice patterns, rather than HDx. Furthermore, Kt/V was higher in the HDx group, but the authors did not standardize dialysis dosing, making it difficult to attribute effects to HDx or to other causes of increased dialysis adequacy. Hemoglobin levels, albumin, hsCRP were not statistically different in the two arms. All investigators are employees of RTS Ltd, Columbia, an affiliate of Baxter Healthcare. The study was supported by Renal Therapy Services-Columbia, an independent entity owned by Baxter International, Inc.

Incomplete Manuscripts

This is the fourth and final grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the incomplete manuscripts which the applicant provided as follows:

- Bolton S, et al.¹³⁴ is a manuscript provided by the applicant and is unfinished. It describes a crossover study of patients previously treated with high-flux HD and switched to Theranova. Patient reported outcome measures (PROMs) suggested decreased self-reported

¹³³ Sanabria RM, Vesga JI, Ariza J, Sanchez R, Suarez A, Bernardo A, Rivera A. Expanded Hemodialysis and its effects on hospitalization and medication usage: an exploratory study. (in submission).

¹³⁴ Bolton S, Gair S, Matthews M, Stewart L, McCullagh N, A 1-year routine assessment of patient-reported symptom burden after implementing expanded hemodialysis, 2019. (in process).

dialysis recovery time and symptom burden, especially at 6 months. However, regression to the mean appeared common, and there was no control group.

- Lim J, et al.¹³⁵ is a manuscript provided by the applicant, reporting a randomized trial comparing MCO to high-flux HD, with 50 patients undergoing 12 weeks of treatment in Korea. The study was small, and the authors performed a large number of statistical tests comparing quality-of-life outcomes, with only a couple statistically significant. Without adjusting p-values for the number of statistical test, the risk for Type 1 error is large and not unexpected. A second trial suggested lower medication doses, but again results were statistically significant only for a few of the parameters of interest. The study is small and requires replication at additional centers to confirm results.

- Lim J-H, et al.¹³⁶ is a manuscript provided by the applicant, reporting a randomized trial comparing MCO to high-flux HD, with 50 patients undergoing 12 weeks of treatment in Korea. Its purpose was to evaluate the effects of ESA resistance of HD using a MCO dialyzer. The number of registered patients was small and the study duration not long enough to assess definite results. Also, the study was not blinded to clinicians, which may have affected the ESA and iron supplementation prescriptions. Additional studies need to be performed to assess clinical outcomes.

(e) Comments by the Members of the CMS TPNIES Work Group

The CMS TPNIES Work Group consists of CMS Medical Officers, senior staff, a senior

¹³⁵ Lim J, Park Y, Yook J, Choi S, Jung H, Choi J, Park S, Kim C, Kim Y, Cho J. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality-of-life outcomes in maintenance hemodialysis patients. (in submission).

¹³⁶ Lim J-H, Yook J-M, Choi S-Y, Jung H-Y, Choi, J-Y, Park S-H, Kim C-D, Kim Y-L, Cho H-H. Novel Medium Cut-Off Dialyzer Improves Erythropoiesis Stimulating Agent Resistance in Maintenance Hemodialysis Patients: A Randomized Control Trial. (in submission).

technical adviser, a biomedical engineer and contracted physicians, including nephrologists. All materials sent by the applicant were reviewed by the members of the CMS TPNIES Work Group. The members of the CMS TPNIES Work Group voiced the specific concerns regarding the evidence submitted for proof of eligibility via the SCI criteria. While Theranova represents a unique technology, the CMS TPNIES Work Group noted that the current evidence supporting SCI is lacking but that other evidence may be forthcoming during the comment period. It is too early to tell if the patient-recorded outcomes, such as fewer cardiovascular events, are significant because of the small numbers in the studies. Specifically, a study for infection was cited with an N=20; another had an N=10. Also, the definition of the infection was vague. Although hospitalization rates are discussed in the articles, the cause of the hospitalization was unknown. Patient lab results should be correlated with patient-reported results. In the submitted articles, the studies are all open-label and observational, with tenuous findings; there should be larger studies focused on the U.S. dialysis population's patient health outcomes; the patients need to be blinded in these studies.

The background information provided by the applicant and researched by the group is conflicting. This may be due to the variation in the location of the studies, including Columbia, France, Belgium, England, Ireland, Australia, New Zealand, and Korea. One of the CMS TPNIES Work Group members suggested a meta-analysis be done, along with the heterogeneity of dialysis care in those countries as compared to the care received by the Medicare population in the U.S.

At this time, while HDx appears to be a promising technology, the CMS TPNIES Work Group has concerns that the current state of evidence insufficiently demonstrates SCI in Medicare patients undergoing dialysis, but that additional evidence may be forthcoming in the

comment period does not believe that the current state of evidence sufficiently demonstrates SCI in Medicare patients undergoing dialysis. In general, the dialyzer appears to have improved middle molecule clearance. While observational studies show an association between high levels of middle molecules and poor outcomes, these correlations do not prove causation. For instance, a growing body of evidence suggests that protein-bound solutes such as indoxyl sulfate and p-cresol sulfate could be responsible for the uremic syndrome. Conventional HD, HDF, and HDx do not effectively clear protein-bound toxins.

A summary of the current body of evidence is as follows:

- Theranova more effectively removes middle molecules compared to conventional dialysis with high-flux membranes. These include molecules that have varying degrees of plausible toxicity (for example, beta 2 microglobulin to cytokines to endothelial proteins). Because nephrologists have not identified the putative uremic toxin, it is not certain that clearance of these toxins will lead to improved clinical outcomes.

- Although small before and after studies suggest potential clinical benefits from MCO dialyzer membranes compared with conventional HD via high-flux membranes, such as reduced infection, improved itching and restless legs, and shorter recovery time from dialysis, these studies are mostly observational, small in nature, with a high potential for bias. A large, multi-center trial would be necessary to prove substantial benefit from HDx over conventional HD.

- Several small studies suggest that MCO dialyzer membranes are comparable to HDF in removal of middle molecules, but online HDF is not generally available in the U.S.

Furthermore, online HDF has not consistently shown to improve health outcomes relative to conventional HD with high-flux membranes.

- There may be increased removal of albumin with MCO membranes compared to conventional high-flux dialysis, which could have negative health consequences.

- A large randomized controlled clinical trial examining the effects of removing larger molecules did not demonstrate clinical benefits from removing larger molecules, although it did not examine newer technologies which are more effective. This negative study provides reason to be somewhat skeptical about the benefits of HDx over HD.

- Following the FDA-requested 6-month clinical study to validate efficacy of large toxin removal and safety, the applicant stated that it anticipates FDA marketing approval in May 2020. However, we note that, per the application, safety is defined in part by albumin loss. At this time we do not believe the clinical trials included safety and efficacy studies for the large middle molecules the applicant asserts to be the cause of inflammation. Therefore, the perceived clinical benefits of providing clearance of those large middle molecules were not assessed in rigorously conducted, randomized clinical studies.

In summary, while HDx is a promising new technology, there is insufficient evidence at this time to demonstrate a clear clinical benefit for Medicare dialysis patients. However, additional evidence may be forthcoming in the comment period. Therefore, we are inviting public comment as to whether Theranova meets the TPNIES SCI criteria.

b. Tablo[®] Cartridge for the Tablo Hemodialysis System

(1) Outset Medical Application

For CY 2021, Outset Medical submitted an application for the TPNIES for the Tablo[®] Cartridge for use with the Tablo[®] Hemodialysis System. The applicant stated that the Tablo[®] Cartridge is intended to substantially improve the treatment of Medicare beneficiaries with ESRD by removing barriers to home dialysis.

The applicant noted that the Tablo[®] Cartridge is necessary to operate the Tablo[®] Hemodialysis System for use in home. The cartridge is comprised of a pre-strung blood tubing set and series of sensor-receptors mounted to a user-friendly organizer, and together these are referred to as the Cartridge. The blood tubing set comprises a blood pump tubing segment that interfaces with a peristaltic (blood) pump mounted on the inner front panel of the Tablo[®] console and arterial and venous lines that connect to the corresponding lines on the patient. Additional components to the cartridge include consumable supplies: bicarbonate and acid concentrate jugs and straws, and an adapter for disinfectant use.

The applicant stated that the blood tubing set is primarily comprised of one arterial line and one venous line and is enhanced with a recirculating adaptor, a bifurcated saline line, a pressure transducer protector, a drip chamber with clot filter, and an arterial pressure pod.

According to the applicant, in addition to the blood lines, there is an integrated saline line that enables automatic priming as well as monitored delivery of saline boluses during treatment. There is also an infusion line and two infusion ports (arterial and venous) for manual delivery of medicine, anticlotting agents, and blood sampling.

In describing what the Tablo[®] Cartridge does, the applicant states that it was designed with features to seamlessly integrate with sensors on the front panel of the console (for example, air sensing, arterial and venous pressure sensing) and to reduce touch points during priming and blood return (for example, recirculating adapter and bifurcated saline line) to minimize contamination. The blood pump draws blood from the patient into the blood tubing set and passes the blood through a dialyzer before returning the treated blood to the patient.

The applicant specifically stated that the Tablo[®] Hemodialysis System includes the Tablo[®] Cartridge. In its entirety, it has been specifically designed for patient-driven self-care

using an iterative human factors process, with key design objectives being to facilitate learning and to minimize device training time.¹³⁷ Human factors studies performed in a laboratory setting have demonstrated that patients can accurately learn and manage the Tablo[®] Hemodialysis System after a brief training period.^{138,139} A recent prospective, multicenter, open-label, crossover trial comparing in-center and in-home HD using Tablo[®] Hemodialysis System further supports the clinical efficacy, safety, and ease of use of the system.¹⁴⁰

The applicant stated that the Tablo[®] Hemodialysis System is the first and only all-in-one technology and includes a number of features that make it new and different from current standard of home dialysis care. These unique features include 1) A single-use Tablo[®] Cartridge with user-friendly pre-strung blood, saline, and infusion tubing and an integrated blood pressure monitor that interfaces with the console to enable automated features such as air removal, priming, and blood return which minimize user errors, save time and streamline the user experience;¹⁴¹ 2) on demand water and dialysate production using a standard tap water source, eliminating the need for time-consuming advance water preparation, bagged dialysate or dialysate batching;¹⁴² 3) a consumer-centric touchscreen interface that guides users with step-by-step instructions including non-technical language, animation, and color-coded parts, to enable easier training, faster set-up and simpler management including clear alarm explanations and

¹³⁷ Alvarez, Luis, et al. "Clinical Experience with a New Hemodialysis System Designed for In-Center Self-Care Hemodialysis." *Self-Care*, vol.8, no. 3, 2017, pp. 12-18. *Self-Care* vol. 8, no. 3, 2017, pp.12–18

¹³⁸ Wilcox, Stephen B., et al. "Results of Human Factors Testing in a Novel Hemodialysis System Designed for Ease of Patient Use." *Hemodialysis International*, vol. 20, no. 4, 16 May 2016, pp. 643–649. doi:10.1111/hdi.12430

¹³⁹ Alvarez, Luis, et al. "Tablet-Based Training for In-Center Self Dialysis -A Pilot Study." *Journal of the American Society of Nephrology*, vol. 27, no. Abstract Edition, Nov. 2016, p. 895A.

¹⁴⁰ Plumb, Troy et al. "Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis." *Hemodialysis International*, Online, 2019, DOI:10.1111/hdi.12795.

¹⁴¹ Outset Medical, "Safety Reference Guide." DOC-0004336 Rev 04, 2019.

¹⁴² Outset Medical, "Tablo Preconfigured System White Paper." DOC-0004252 Rev 01, 2019.

resolution instructions;¹⁴³ and 4) electronic data capture and automatic wireless transmission to eliminate the need for manual record keeping by the patient, care partner, or nurse.¹⁴⁴

The applicant asserted, both in the written application and at an in-person meeting with CMS, that the observational studies with the Tablo[®] Hemodialysis System were able to achieve CMS adequacy targeted on three times per week dialysis at an average treatment time of less than 4 hours. Tablo[®] has demonstrated the ability to treat to adequacy targets within the Medicare standard reimbursement of three treatments per week.

The applicant has not submitted an application for pass-through payments under the Medicare OPPS or the NTAP program under the Medicare IPPS for the Tablo Hemodialysis System, including the Tablo[®] Cartridge.

This application for TPNIES is only for the Tablo[®] Cartridge and its components for use in the home, which the applicant stated that it intended to begin marketing in March 2020 following FDA clearance of the Tablo[®] Hemodialysis System for home use. On March 31, 2020, Outset Medical received FDA clearance to market the device for use in the home, and CMS received a copy of this letter.

The applicant submitted a Premarket Notification 510(k) for marketing clearance of Tablo[®]. Previous 510(k) authorizations for the Tablo[®] Hemodialysis System and Tablo[®] Cartridge were for hospital and outpatient clinic use only. The applicant could not use or market the Tablo[®] Cartridge in the home setting until the Tablo[®] Hemodialysis System was granted marketing authorization by the FDA (note: Table Hemodialysis System and cartridge was granted FDA market authorization in November 2016). While the cartridge was previously cleared through a

¹⁴³ Alvarez, Luis, et al. "Tablet-Based Training for In-Center Self Dialysis -A Pilot Study." *Journal of the American Society of Nephrology*, vol. 27, no. Abstract Edition, Nov. 2016, p. 895A.

¹⁴⁴ Outset Medical, "Tablo Information Security Design White Paper." DOC-0003639 Rev 03, 2019.

separate 510k and was not necessary to include in the submission for marketing clearance for home use, the Tablo® Hemodialysis System cannot be operated without the Tablo® Cartridge. According to the applicant, the cartridge was included in the use instructions for the home approval.

The applicant noted that the Tablo® Cartridge is not currently available for marketing in the home setting. As explained above, the applicant intended to begin marketing in the home setting in March 2020, after the FDA clears the Tablo® Hemodialysis System for marketing for home use. The applicant expected the first shipments of the Tablo® Cartridge for use in the home to occur March 2020. However, it is our understanding that to-date, the first patient to start training is scheduled to begin June 1, 2020.

The applicant does have an IDE to study the Tablo® Hemodialysis System's safety and efficacy for use in the home, which has been completed as of the filing of the TPNIES application. The applicant stated that the IDE would be closed once marketing authorization for the use of the Tablo® Hemodialysis System in the home is approved. The IDE study reference number is G140098. The Tablo® Cartridge is assigned a Class II device category.

The applicant stated that it would submit a HCPCS application for the Tablo® Cartridge in advance of the September 1, 2020 deadline.

The applicant identified and described how the new and innovative renal dialysis equipment or supply meets the criteria for SCI over existing renal dialysis services. The applicant states the Tablo® Cartridge is necessary to operate the Tablo® Hemodialysis System and therefore enables the system to deliver the treatments that meet CMS's SCI criteria.

The applicant states that the Tablo® Hemodialysis System enables a treatment option for a patient population unresponsive to, or ineligible or, currently available treatments. As

supporting background material, the applicant notes that home HD is a highly underutilized treatment for ESRD patients. Currently 90 percent of patients receive HD in a clinic. Fewer than 2 percent have HD treatment at home. Contributing to this low penetration rate is also a high dropout rate with the incumbent home devices of 25 percent and 35 percent at 12 and 24 months, respectively.¹⁴⁵ The barriers to home dialysis adoption and retention have been well studied and include: 1) treatment burden for patients and care partner fatigue; 2) technical challenges operating HD machine; 3) space, home modifications, and supplies management; 4) patients not wanting medical equipment in the home; and 5) safety concerns.^{146,147} The applicant asserts that Tablo[®] is the first new home HD system in over 15 years, designed to address many of the above-mentioned barriers that currently result in patients resigning themselves to in-center care and/or stopping home modalities due to the associated burden of self-managed therapy. Among other things, the objective of this order is for 80 percent of ESRD patients starting kidney replacement therapy (KRT) with a transplant or home dialysis by 2025.¹⁴⁸ The applicant states that this goal will require a multi-faceted solution, inclusive of less burdensome technology, to address the key barriers to home dialysis.

The applicant believes that the Tablo[®] Hemodialysis System has the potential to significantly increase home dialysis. The applicant conducted an IDE study for the primary purpose of evaluating the safety and efficacy of Tablo[®] Hemodialysis System use in the home

¹⁴⁵ Sehasi, Rebecca et al. Factors Associated With Discontinuation of Home Hemodialysis, *American Journal of Kidney Disease*, Volume 67, Issue 4, 2016, Pages 629-637.

¹⁴⁶ Seshasai, R.K., et al. The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. *Hemodialysis International*, 23: 139-150, 2019. doi:10.1111/hdi.12713.

¹⁴⁷ Chan, Christopher T. et al. Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference

Outcomes Report, Mar 2019, *American Journal of Kidney Diseases*, Volume 73, Issue 3, 363 – 371.

¹⁴⁸ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Advancing American Kidney Health*, July 10, 2019

setting. The applicant stated that the results from the IDE study demonstrate the following: 1) patients will opt for home dialysis if the Tablo® Hemodialysis System is available; 2) patients have confidence in the safety and efficacy of the Tablo® Hemodialysis System; 3) the unique features of the Tablo® Cartridge as part of the Tablo® Hemodialysis System simplify set-up and use; and 4) the wireless transmission of data feature is reassuring to patients because it relieves patients of the burden of recording and fear that the patient may forget to document some aspect of treatment. The applicant claims that the IDE study results show that these key features will facilitate growth and ongoing use of the Tablo® Hemodialysis System in the home setting.

During the course of the study, with an average treatment time of 3.4 hours, twenty-eight out of thirty patients completed all phases of the trial and no patient dropouts occurred during the in-home phase. There is only one other mobile HD machine on the market. Its IDE, based on six times per week therapy at an average treatment duration of 2.8 hours, showed a higher drop-out rate (19 percent vs Tablo's® 7 percent) and lower adherence to treatment at home (89 percent vs Tablo's® 99 percent).^{149,150}

The applicant asserts that the Tablo® Hemodialysis System significantly reduces training time for both patients and their caregivers, improving training completion and reducing patient technique failure and care partner burden. The applicant state that the cartridge element of the Tablo® Hemodialysis System removes many of the manual steps and minimizes both set up time, and the need to make difficult connections, which requires training to avoid contamination. In human factors testing submitted to the FDA, the use of the cartridge resulted in 90 percent of the

¹⁴⁹ Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, 11: 468-477 2007 doi:10.1111/j.1542-4758.2007.00229.x.

¹⁵⁰ Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. *Hemodialysis International* 2019l. doi:10.1111/hdi.12795

users being able to set up Tablo[®] in under 10 minutes.¹⁵¹ The applicant stated that the Tablo[®] Hemodialysis System home IDE data demonstrates that on average it takes 3.5 training sessions to learn the Tablo[®] Hemodialysis System compared to 14.5 sessions on the device that is the current standard of care for home HD.¹⁵² The applicant asserts that reduced training time increases likelihood of successful completion, reduces patient technique failure, and decreases caregiver burden. The applicant notes the following: 1) the graphical user interface guides users through the treatment and eliminates the need for memorization and mental math; 2) sensors and automation eliminate multiple manual steps in treatment set-up; and 3) contextual alarms instantly alert patients to any issues with their treatment and provide video and text direction on how to resolve them. This is in comparison to numerical alarm codes with the incumbent device that requires reference to the user manual or memorization with no video guidance available.

The applicant states that the Tablo[®] Hemodialysis System significantly reduces set up and treatment time reducing treatment burden, improving retention at home, and reducing the need for and involvement of a care partner. The applicant noted that data from Outset Medical's Tablo[®] Hemodialysis System home IDE trial showed that a patient could set up the Tablo[®] Hemodialysis System in 9.2 minutes.¹⁵³ With the average number of treatments of 3.6 per week for an average duration of 3.4 hours,¹⁵⁴ a Tablo[®] Hemodialysis System user treating 4 times per week can expect to spend approximately 14 hours a week preparing for and conducting treatments, versus 40 hours a week on the incumbent device for patients who batch

¹⁵¹ Alvarez, Luis, et al. "Clinical Experience with a New Hemodialysis System Designed for In-Center Self-Care Hemodialysis." *Self-Care*, vol.8, no. 3, 2017, pp. 12-18. *Self-Care* vol. 8, no. 3, 2017, pp.12-18

¹⁵² Chahal, Yaadveer, Decreased Time to Independence with the Tablo Hemodialysis System: A Subset Analysis of the Tablo Home Clinical Trial, Abstract accepted for the National Kidney Foundation Spring Clinical Meeting 2020.

¹⁵³ Outset Medical subset analysis of Home IDE Trial data on set up time for Tablo Cartridge and concentrates

¹⁵⁴ Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. *Hemodialysis International* 2019l. doi:10.1111/hdi.12795

solutions.^{155,156} The applicant states that this significant reduction in setup and treatment time is a result of software and workflow improvements incorporated in the Tablo[®] Hemodialysis System and its cartridge, many of which were driven by patient feedback. Reducing overall treatment burden improves modality retention at home on behalf of the patient and limits the care partner burden by reducing the need for their active involvement in treatment.

The applicant states that the cartridge portion of the Tablo[®] Hemodialysis System is pre-strung and requires only two connections to operate as compared to other systems that require stringing, hanging, snapping, and tapping multiple lines. In the home IDE time set up of dialysate concentrates, the Tablo[®] Cartridge took less than 12 minutes on average. With an average time of 8 minutes, an uninterrupted patient can initiate therapy in as little as 20 minutes.¹⁵⁷ This is a significant improvement in the standard of care, which can take approximately 45 minutes.¹⁵⁸ The applicant asserts that the Tablo[®] Hemodialysis System's automatic and integrated sensors and automated degassing and priming also make the machine easier to use and quicker to set up and get to treatment.

The applicant states that the Tablo[®] Hemodialysis System is the only system with a fully integrated water treatment system that allows for real-time water purification and dialysate produced on demand with no need to batch solutions or hang bags of dialysate. In addition, the applicant noted that it requires only a standard, grounded electrical outlet and Environmental

¹⁵⁵ NxStage Medical, Transitional Dialysis Care Operational Guidance, June 2019,

<https://www.nxstage.com/wpcontent/uploads/2019/06/APM2548-Rev-B-TDC-Operational-Guidance.pdf>.

¹⁵⁶ Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, 11: 468-477 2007 doi:10.1111/j.1542-4758.2007.00229.x.

¹⁵⁷ Outset Medical subset analysis of Home IDE Trial data on set up time for Tablo Cartridge and concentrates.

¹⁵⁸ Informal interviews with NxStage patients

Protection Agency quality tap water to operate, obviating the need to store bags of dialysate in the home, significantly reducing the number of supplies patients need to receive each month.

The applicant notes that the Tablo[®] Hemodialysis System reduces patient/care partner burden and technique failure. Specifically, the applicant stated that automation of processes such as prime and rinse back reduces the overall number of treatment related steps. In addition, the applicant says that the Tablo[®] Hemodialysis System's easy to use touchscreen interface walks users through each step of setup, treatment, and take down; the treatment information displays data that patients most wanted to see. The applicant asserts that this automation and patient-centric design reduces technique failure as evidenced by results from the IDE study, which demonstrated a significant increase in treatment adherence and high rate of study completion compared to the current standard.

The applicant further states that the Tablo[®] Hemodialysis System eliminates documentation burden and reduces reporting errors, and that it is the only HD system with 2-way wireless transmission delivering HIPAA compliant data to the healthcare provider without any need for additional equipment. This frees patients from the need to manually document treatment data by hand or on a separate tablet and ensures higher data accuracy.

The 28 patients who entered the home phase of the Tablo[®] Hemodialysis System home IDE answered weekly if they needed help with treatment over the prior seven days. The applicant stated that by the end of the study, 216 of 224 possible responses were obtained. The care partner burden rating for prior in-home patients who were previously dialyzing on the incumbent device decreased from 3.1 to 2.4 on Tablo[®]. Among prior in-home patients, 69 percent of patients reported needing help from a trained individual with their prior device with 46 percent of respondents stating the help needed was device related, 15 percent related to

cannulation alone, and 8 percent reported other. By contrast, while on Tablo[®], only 38 percent of patients reported needing help with treatment -- only 22 percent needed help related to use of Tablo[®] while 16 percent needed help related to cannulation. The applicant asserts that this data underscores a significant decrease in patients needing assistance with treatment at home.

The applicant states that Tablo[®] Hemodialysis System's unique features increase patient safety and satisfaction. The applicant notes that Tablo[®] Hemodialysis System's integrated, 2-way wireless connection provides clinicians with the ability to monitor patients in real time without any separate equipment necessary. The applicant asserts that the Tablo[®] Hemodialysis System is the only HD technology with this function, which allows for early identification and intervention by a patient's healthcare team as a key safety feature. At 34 inches tall, Tablo[®] Hemodialysis System user interface matches the height of a user while seated in a standard dialysis chair allowing patients to directly, and quickly engage with the integrated touch screen to view progress of the treatment, resolve alarms, and adjust certain functions to tailor the treatment to his or her needs. As an example, a patient with limited mobility can reach the interactive touch screen to adjust the flow rate if they feel cramping coming on. The IDE generated data that demonstrated how the technology enabled more rapid resolution of alarms. During the home arm of the study, patients were able to resolve alarms on the Tablo[®] Hemodialysis System in 5 seconds.¹⁵⁹ The applicant asserts that rapid resolution of alarms and enhanced communication improve safety by facilitating rapid correction of any treatment related events, limiting treatment interruptions and improving communication between the patient and provider.

¹⁵⁹ Wilcox, Stephen B. et al., Results of human factors testing in a novel hemodialysis system designed for ease of patient use, *Hemodialysis International* 2016; 20:643-649.

Once approved for home use, the applicant states that the Tablo® Hemodialysis System will provide a simpler, easier to use system that is likely to increase the number of people who are able to receive and remain on dialysis at home by addressing many of the well-documented, key barriers to home dialysis reported in peer-reviewed literature.

In addressing the way in which the Tablo® Hemodialysis System with its cartridge significantly improves clinical outcomes relative to the renal dialysis services previously available, the applicant focused on hospitalization and quality of life. The applicant stated that the Tablo® Hemodialysis System's 2-way wireless connection allows for real-time intervention to prevent hospitalizations. The applicant stated that during the Tablo® Hemodialysis System home IDE, the patients using the Tablo® Hemodialysis System had an all cause admission rate of 426 per 1,000 patient years. In the general dialysis population, the all cause admission rate is 1688 per 1,000 patient years and for patients who do PD, the hospitalization rate is 1460 per 1,000 patient years, highlighting that the Tablo® Hemodialysis System may significantly reduce hospitalizations and lower cost of care.¹⁶⁰ The applicant states that Tablo® Hemodialysis System's integrated, 2-way wireless connection provides clinicians the ability to monitor patients in real time without any separate equipment necessary, and is the only equipment with this embedded functionality which allows for earlier identification and intervention by a patient's healthcare team and could prevent unnecessary hospitalizations for dialysis related events or missed treatments.

The applicant stated that the Tablo® Hemodialysis System can effectively deliver adequacy with 3-4 treatments per week, potentially reducing Medicare expenditures on

¹⁶⁰ United States Renal Data System. 2019 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2019, Executive Summary Reference Table G2.

additional dialysis treatments per week. The applicant said that among home HD patients, Medicare payment for dialysis treatments was highly variable across different regions at 3.5 to 5.7 per week.¹⁶¹ In the IDE for the Tablo[®] Hemodialysis System, the applicant asserted that there was effectively delivered adequacy with 4 treatments per week with an average session length of 3.4 hours, resulting in an average weekly treatment duration of ~13.6 hours. An average weekly standard Kt/V of 2.8 was achieved and 94 percent of patients achieved an ultrafiltration rate within 10 percent of the prescribed value.¹⁶² The applicant noted that a previous study of Tablo[®] Hemodialysis System used in the clinic showed achievement of a spKt/V of 1.2 based on 3 treatments per week including for patients over 90kg. While the frequency of how often patients should receive dialysis is a clinical decision that should be made between the physician and the patient, the Tablo[®] Hemodialysis System is the only mobile HD system with clinical data showing achievement of adequacy standards and ultrafiltration endpoints for 3 and 4 treatments per week regardless of the size of the patient.^{163,164} The applicant concludes that in this way, the Tablo[®] Hemodialysis System has the potential to reduce Medicare expenditures on the billing of additional dialysis treatments.

¹⁶¹ Wilk, Adam S. et al., Persistent Variation in Medicare Payment Authorization for Home Hemodialysis Treatments Health services research vol. 53,2 (2018): 649-670.

¹⁶² Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International, 2019. doi:10.1111/hdi.12795

¹⁶³ Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

¹⁶⁴ Alvarez, Luis and Chertow, Glenn, Real World In-Center Urea Clearance Experience with a Novel Hemodialysis System, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

The applicant states that Tablo® Hemodialysis System’s ability to deliver adequacy on fewer treatments per week may also reduce vascular access complications due to frequent cannulation.¹⁶⁵

The applicant submitted several examples in four topics to demonstrate how the Tablo® Hemodialysis System improves the quality of life. The applicant noted that patients value having a high-quality daily life, ability to live well, and feeling empowered to control their outcomes over mortality.¹⁶⁶ The applicant asserted that the use of the Tablo® Hemodialysis System at home allows patients to have an improved quality of life and control over their outcomes.

The first topic of improved quality of life focused on sleep and reduction in fatigue. The applicant noted that kidney patients participating in an international research collaborative to identify outcome measures most important to them ranked fatigue/energy as their top priority.¹⁶⁷ The applicant reported that patients in the IDE who were on home HD with an incumbent device experienced a 14 percent improvement in waking up feeling rested while on the Tablo® Hemodialysis System. Additionally, 22 percent fewer patients reported having trouble staying asleep, and 15 percent fewer patients reported waking up several times during the night while on the Tablo® Hemodialysis System.¹⁶⁸ The applicant asserted that this data shows that the Tablo®

¹⁶⁵ Agency for Healthcare Quality and Research, End Stage Renal Disease in the Medicare Population: Frequency and Duration of Hemodialysis and Quality of Life Assessment, Draft Technology Assessment, Agency for Healthcare Quality and Research November 22, 2019.

¹⁶⁶ Urquhart-Secord, Rachel et al Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Sept. 2016, Volume 68, Issue 3, 444 – 454

¹⁶⁷ Ibid

¹⁶⁸ Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International. doi:10.1111/hdi.12795

Hemodialysis System is able to make a clinically significant improvement in the quality of life indicator most valued by dialysis patients.

The second topic of improved quality of life discussed by the applicant was improvement in the patients' experience of hypotensive events. The applicant submitted that investigators report that a drop in blood pressure was also ranked in the top 10 of symptoms rated by patients that impact their quality of life.¹⁶⁹ The applicant reported that a total of 12 (40.0 percent) and 8 (26.7 percent) subjects reported hypotensive events during the Tablo[®] Hemodialysis System treatments during the In-Center and In-Home treatment periods, respectively, compared to 27 (90.0 percent) subjects reporting hypotensive events at baseline on another HD machine. All patients who reported hypotensive events while on dialysis in the study had also reported hypotension in their baseline history.¹⁷⁰

The third topic of improved quality of life was that fewer patients reported feeling cold. The applicant reported that a total of 15 (50.0 percent) subjects during the in-center treatment period and 12 (40.0 percent) subjects during the In-Home treatment period reported feeling cold while dialyzing on the Tablo[®] Hemodialysis System compared to 28 (93.3 percent) subjects who reported feeling cold at baseline while dialyzing on another dialysis machine. The applicant asserted that the Tablo[®] Hemodialysis System's design results in tight control of dialysate temperature and allows patients to easily and accurately adjust temperature through the graphical user interface.¹⁷¹

¹⁶⁹ Urquhart-Secord, Rachel et al. Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study *American Journal of Kidney Diseases*, Sept. 2016, Volume 68, Issue 3, 444 – 454

¹⁷⁰ Outset Medical Data from Home IDE Trial, pg 33 of clinical report submitted to the Food and Drug Administration, data table 43, 2019.

¹⁷¹ Ibid.

The fourth topic of improved quality of life was patient preference for the Tablo[®] Hemodialysis System. The applicant stated that the Kidney Health Initiative (KHI), a public private partnership between the FDA and the American Society of Nephrology, Renal Replacement Therapy (RRT) Roadmap prioritizes patient-centered innovation, which includes dialysis equipment that is more portable, removes barriers to home dialysis and improves patients ease of use to increase opportunities for self-care. The RRT, which was developed in conjunction with patients, also prioritizes patient centered outcomes and technology that reduces disruption in social and family life.¹⁷² The applicant reported that among prior home HD users in the IDE trial, 85 percent reported they preferred the Tablo[®] Hemodialysis System to their current equipment.¹⁷³ Patients also rated Tablo[®] as easier to set-up, treat, and take down. Ease of use ratings comparing the patient's prior device to Tablo[®] were as follows: Set up -- 3.5 to 4.5, Treatment -- 3.3 to 4.6, Take Down -- 3.8 to 4.6.¹⁷⁴

In summary, the applicant submitted that the Tablo[®] Hemodialysis System has the potential to significantly expand the number of patients who are able to receive home HD and persist on the therapy. The applicant stated that it is an innovative HD system that removes most of the device-related key barriers, reduces dialysis-related symptoms, is mobile and easy to use, and therefore minimizes dialysis-related disruptions in patients' lives.

(2) CMS TPNIES Work Group

(a) Summary of current technology by CMS TPNIES Work Group

¹⁷² Kidney Health Initiative, Technology Roadmap for Innovative Approaches to Renal Replacement Therapy, prepared by the Nexight Group, October 2018, https://www.asnonline.org/g/blast/files/KHI_RRT_Roadmap1.0_FINAL_102318_web.pdf.

¹⁷³ Chahal, Yaadveer, Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial, Abstract Accepted by the National Kidney Foundation Spring Clinical Meeting 2020.

¹⁷⁴ Outset Medical Data from Home IDE Trial, pg 33 of clinical report submitted to the Food and Drug Administration, data table 43, 2019.

Patients with ESRD who are not able to receive a kidney transplant must undergo maintenance dialysis therapy. Patients can receive dialysis 3-4 days a week at an in-center HD facility, or they can administer dialysis themselves at home. Due to the reliance on outpatient dialysis units, numbers of patients utilizing home dialysis in the U.S. have remained low. In 2017, only 10.8 percent of US dialysis patients received home-based therapies.¹⁷⁵ Patients and caregivers cite concerns with self-cannulation, fears of needle disconnect and complications.¹⁷⁶ Home dialysis use is lower than many other rich countries.¹⁷⁷

Most patients administering dialysis at home use PD. However, home HD has more recently re-emerged as an alternative way for patients to dialyze at home. Home HD may offer many of the advantages observed with peritoneal dialysis, such as increased flexibility and quality-of-life benefits. However, adoption of home HD has been limited, with approximately only 1 percent of ESRD patients utilizing this modality.¹⁷⁸

Observational studies do not indicate significant differences in survival when comparing home dialysis to in-center dialysis.¹⁷⁹ Yet, there are some potential benefits to home-based dialysis. Prior analyses have noted that home-based dialysis affords greater patient flexibility, improved quality of life,¹⁸⁰ increased likelihood of employment,¹⁸¹ and improved cost.¹⁸²

¹⁷⁵ United States Renal Data System (USRDS). 2019 Annual Data Report: Reference Tables.

<https://www.usrds.org/reference.aspx>. Last Access Date Feb 20, 2020.

¹⁷⁶ Young BA, Chan C, Blagg C, Lockridge R, Golper T, Finkelstein F, Shaffer R, Mehrotra R; ASN Dialysis Advisory Group. How to overcome barriers and establish a successful home HD program. *Clin J Am Soc Nephrol*. 2012 Dec;7(12):2023-32. doi: 10.2215/CJN.07080712. Epub 2012 Oct 4.

¹⁷⁷ Wilkie M. Home dialysis-an international perspective. *NDT Plus*. 2011 Dec;4(Suppl 3):iii4-iii6.

¹⁷⁸ Mailloux LU, Blagg CR. Berns JS (ed.) *Home Hemodialysis*. Uptodate. Nov 18, 2016.

¹⁷⁹ Chiu YW, Jiwakanon S, Lukowsky L, Duong U, Kalantar-Zadeh K, Mehrotra R. An update on the comparisons of mortality outcomes of hemodialysis and peritoneal dialysis patients. *Semin Nephrol*. 2011;31:152-158.

¹⁸⁰ Rubin HR, Fink NE, Plantinga LC, Sadler JH, Klinger AS, Powe NR. Patient ratings of dialysis care with peritoneal dialysis vs hemodialysis. *JAMA*. 2004;291:697-703.

¹⁸¹ Muehrer RJ, Schatell D, Witten B, Gangnon R, Becker BN, Hofmann RM. Factors affecting employment at initiation of dialysis. *Clin J Am Soc Nephrol*. 2011 Mar;6(3):489-96.

¹⁸² Berger A, Edelsberg J, Inglese GW, Bhattacharyya SK, Oster G. Cost comparison of peritoneal dialysis versus hemodialysis in end-stage renal disease. *American Journal of Managed Care*. 2009;15:509-518.

However, regarding cost comparisons, it is important to note that many cost analyses of home-based dialysis include estimates from peritoneal dialysis. The machines for HD are costly and there may be higher rates of infection from self-cannulation, which could offset any savings. Since such a small percentage of patients receive home-based HD, it is challenging to know actual cost without pooling it with peritoneal dialysis estimates. Regardless, due to an executive order issued in 2019, economic incentives for home dialysis (both peritoneal and home HD) were increased with the goal of expanding its use.¹⁸³

(b) Description of new technology by the CMS TPNIES Work Group

The first personal HD system on the market was called the Aksys personal HD (Aksys PHD) system. It created its own ultrapure dialysate and was FDA cleared in 2002. It later underwent recall in 2006 due to marketing inconsistencies with system design.¹⁸⁴ Eventually, the manufacturer shut down operations after difficulties in securing financing.¹⁸⁵ In addition to these issues, it was a large machine that required significant patient utility resources and specialized maintenance.¹⁸⁶ Around this time, development of the Allient dialysis system began, which utilizes a sorbent column to regenerate dialysate from tap water.¹⁸⁷ It is still in development for potential home based therapy.

¹⁸³ The White House. Executive Order on Advancing American Kidney Health. July 10, 2019. <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/> Last Access Date Feb 18, 2020.

¹⁸⁴ Food and Drug Administration. Class 2 Device Recall Aksys PHD Personal Hemodialysis System. Medical Devices Database. June 2006. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=46686>

¹⁸⁵ Modern Healthcare. Dialysis machine firm Aksys shuts down. Feb 21, 2007. <https://www.modernhealthcare.com/article/20070221/NEWS/70221010/dialysis-machine-firm-aksys-shuts-down>. Last Access Date Feb 18, 2020.

¹⁸⁶ Mailloux LU, Blagg CR, Berns JS (ed.) Home Hemodialysis. Uptodate. Nov 18, 2016.

¹⁸⁷ Ash SR. The Allient dialysis system. Semin Dial. 2004 Mar-Apr;17(2):164-6.

Several home dialysis machines are currently available. Recently, the NxStage[®] System One dialysis machine was FDA approved for 510(k) premarket status in August 2017.¹⁸⁸ It has a smaller profile than the Aksys machine but requires 4 to 6 large bags of ultrapure dialysate and comes with home storage requirements. The NxStage[®] PureFlow SL was subsequently developed for use with the NxStage[®] System One. It allows patients to prepare dialysate from tap water with a reduced need to store dialysate bags. The NxStage[®] system advertises an easier experience learning how to administer home dialysis. Within this arena, the Tablo[®] Hemodialysis System has recently emerged and been approved for use in hospitals and outpatient settings. The Tablo[®] Hemodialysis System is most comparable to NxStage System One combined with NxStage[®] PureFlow, in that it may be easier to use than conventional home dialysis machines and can be used from a tap water source. The applicant is currently pursuing approval for use of cartridges for the Tablo[®] Hemodialysis System in the home setting. While this application centers on reimbursement of the Tablo[®] Cartridge, this cartridge is only compatible with the Tablo[®] Hemodialysis System. The cartridge is made up of a rigid “Organizer” which mounts the necessary tubing to allow for greater ease in set-up. This self-contained and single-use cartridge houses both the arterial and venous lines, an adaptor to connect the lines, a saline line, and an infusion line. There is also a pressure transducer protector, venous drip chamber with clot filter, and an arterial pressure pod. The applicant noted that the cartridge simplifies connection to the Tablo[®] Hemodialysis System and reduces set-up time. It would seem that this cartridge would be most useful in the home-setting, since hospital and clinic settings would normally have trained personnel to assist with set-up. Although

¹⁸⁸ Food and Drug Administration. Traditional Section 510(k) Premarket Notification Letter, Number K171331. August 24, 2017. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171331.pdf

separate from the Tablo[®] Cartridge, the Tablo[®] Hemodialysis System also performs real-time water purification on demand dialysate production.

A significant challenge to increasing the use of home dialysis includes burn out (or technique failure) and return to in-center HD. According to one recent observational study, approximately 25 percent of patients who initiate home HD return to in-center HD within the first year.¹⁸⁹ A good measure of a home-based system's success would be in its ability to allow patients to remain on the therapy long-term. Failure to maintain home HD, and low use of home HD, may be a result of anxiety and unease that many patients have about performing the treatment themselves (or with the help of care takers).^{190,191,192} This includes fear of self-cannulation in order to access the blood for dialysis and a lack of self-efficacy in performing the therapy. By simplifying the process of setting up dialysis tubing, offered by the Tablo[®] Hemodialysis System cartridge, some patients may be able to successfully perform home HD.

(c) Approvals

The applicant has not previously submitted applications for pass-through or add-on payments. The applicant has received 510(k) marketing clearance for the machine to be used in hospital and outpatient clinic use only. As such, the applicant is pursuing FDA authorization for use in the home setting for February 2020. The Tablo[®] Hemodialysis System cartridge received FDA marketing approval in December, 2019 and the Tablo[®] Hemodialysis System received FDA marketing authorization for home setting in March 2020. The applicant noted that upon

¹⁸⁹ Seshasai RK, Mitra N, Chaknos CM, Li J, Wirtalla C, Negoianu D, Glickman JD, Dember LM. Factors Associated With Discontinuation of Home Hemodialysis. *Am J Kidney Dis.* 2016 Apr;67(4):629-37.

¹⁹⁰ Cafazzo JA, Leonard K, Easty AC, Rossos PG, Chan CT. Patient-perceived barriers to the adoption of Nocturnal Home Hemodialysis. *Clin J Am Soc Nephrol.* 2009;4:784-789.

¹⁹¹ Suri RS, Larive B, Garg AX, et al. Burden on caregivers as perceived by hemodialysis patients in the frequent Hemodialysis network (FHN) trials. *Nephrol Dial Transplant.* 2011;26:2316-2322.

¹⁹² Zhang AH, Bargman JM, Lok CE, et al. Dialysis modality choices among chronic kidney disease patients: Identifying the gaps to support patients on home-based therapies. *Int Urol Nephrol.* 2010;42:759-764

approval, the company plans to ship that same month. The technology had an investigational device exemption for use in the home and which closed after approval of marketing authorization. It is assigned as a Class II device category.

(d) Assessment of Substantial Similarity to Currently Available Technology

The NxStage[®] One is the only home-based HD system that is FDA has approved at this time. The Tablo[®] Hemodialysis System differs from the NxStage[®] in that dialysate is produced on demand whereas the NxStage[®] requires that patients batch dialysate or use pre-filled concentrate with the PureFlow. The Tablo[®] Hemodialysis System also includes a cartridge (which is the portion being evaluated for TPNIES) designed to facilitate the connection of tubing in the appropriate configuration.

This product treats similar patients, notably patients with ESRD requiring HD.

(e) Assessment of SCI (see §§ 413.236(b)(5) and 412.87(b)(1))

The Tablo[®] Hemodialysis System is a treatment modality, not a diagnostic tool. With regard to the question as to whether this new renal dialysis equipment offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we note that patients who are eligible for this treatment would currently be eligible for in-center HD, home HD with currently available treatments, and possibly PD.

(f) Clinical Evidence for Claims of SCI

The applicant included an annotated bibliography in its application. Many of the articles describe the features of the HD system: straightforward and relatively efficient set-up and training, presence of safety features, water purification system, and wireless communication. In terms of clinical outcomes and improvements, the referenced authors have presented or published data on safety, clearance and treatment times, hypotensive events and cold symptoms,

and patient preference. As these are arguably more important considerations, we are focusing on the evidence with those claims of clinical improvement or patient reported outcomes.

Below is a list of references for SCI based on evidence published from several sources. We summarize the studies grouped by listings with the most rigorous review to those with the least rigorous review, specifically, Trials Published in Peer-Reviewed Journals, then Posters and Abstracts, and ending with Unpublished Data.

Trials Published in Peer-Reviewed Journals

- Plumb TJ, et al.¹⁹³ describes the IDE study, which was a prospective, multicenter, open-label crossover trial evaluating in-center versus in-home use of the Tablo[®] Hemodialysis System. Thirty patients underwent a run-in period, 8 weeks of in-center therapy (4 treatments a week), then a 4-week transition period, and finally an 8-week in-home treatment (4 times a week). Authors evaluated efficacy in effective removal of uremic toxins, as measured by a weekly standard Kt/Vurea ≥ 2.1 and a secondary endpoint of delivered ultrafiltration within 10 percent of prescribed. Twenty-eight out of 30 patients completed the study. One patient died from cardiac arrest and the authors felt it was unrelated to the treatments. Another patient withdrew prior to starting in-home HD. There were primary outcomes, secondary outcomes, adverse event rates, alarms per treatment, and alarm response times between the two groups. Patients demonstrated high adherence rates of 96 percent, and 99 percent for the in-center and in-home groups, respectively. There is bias from the open-label study and this is a small study conducted over a short period of 12 weeks total, 4 weeks of in-home dialysis. Long-term and larger studies would

¹⁹³ Plumb TJ , Alvarez L, Ross DL, Lee JJ, Mulhern JG, Bell JL, Abra G, Prichard SS, Chertow GM, Aragon MA. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodial Int. 2020 Jan;24(1):22-28. doi: 10.1111/hdi.12795. Epub 2019 Nov 7.

be helpful to capture any safety signals. Some authors serve as Chief Medical Officer or consultants for Outset Medical.

- Kraus M, et al.¹⁹⁴ is a study involving the comparator technology known as NxStage[®] System, which is a portable HD unit. This was a prospective, open-label, crossover study comparing in-center HD versus home HD in 32 patients over 18 weeks total. The primary endpoint was delivery of 90 percent prescribed fluid volume, which was achieved in similar fashion and >90 percent in both groups. There were statistically significant differences in adverse events, which favored the home HD group. The applicant included this study to demonstrate similar evidence as well as compare time spent in performing the home sessions. Treatment durations were slightly shorter than what was noted in the IDE study above (mean 2.8 hours for NxStage[®] versus mean 3.4 hours with Tablo[®] Hemodialysis System). This study was supported by NxStage[®] Medical Inc.

Posters/Abstracts

- Alvarez, Luis et al.¹⁹⁵ is a retrospective study, 29 patients underwent HD with the Tablo[®] Hemodialysis System at a lower flow rate than what is used in conventional in-center HD. Average treatment times were slightly higher in the Tablo[®] Hemodialysis System group compared to those using non-Tablo[®] systems. After patient weight stratification at 90 kg, authors felt that both groups achieved similar weight changes (extrapolated from pre and post weights), as well as Kt/Vurea change. This research was funded by Outset Medical, Inc.

¹⁹⁴Kraus M, Burkart J, Hegeman R, Solomon R, Coplon N, Moran J, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, 11: 468-477, (2007).

¹⁹⁵ Alvarez L, Spry L, Mulhern J, PPrichard S, Shallall C, Chertow G, Aragon, M, Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

- Alvarez, Luis et al.¹⁹⁶ utilized lower flow rates of 300 ml/min, and evaluated patients as they transitioned to in-center but self-directed HD with Tablo[®] Hemodialysis System. Patients underwent 3 times a week treatment and data was collected over a 3-month period. Based on urea samples and calculated Kt/Vurea, authors concluded that this treatment resulted in adequate clearance.

- Chahal, Yaadveer¹⁹⁷ is a study that focused on the patient experience through surveys and compared the patient's responses to prior in-home and in-center experiences. As part of the IDE study, 13 participants provided survey responses to compare their experience with the Tablo[®] Hemodialysis System to their prior experience with in-home dialysis. Of those 13 participants, 85.6 percent found this system easier to use. While this is promising, the true test of superiority in this realm would be rates of discontinuation at 1 year. Issues of self-cannulation and the burden of this responsibility still remain with this system. The primary study was undertaken by Outset Medical.

Unpublished Data:

- Outset Medical Data¹⁹⁸ is a limited section, in which the applicant submitted cold and hypotensive events while on in-center or in-home HD. From just raw numbers, there were lower percentages of either sign/symptom within the home dialysis group compared to in-center.

(g) Comments of the CMS TPNIES Work Group

Only the Tablo[®] Cartridge portion of the Tablo[®] Hemodialysis System is being evaluated in this application, but it is important to note that it can only be used with the Tablo[®]

¹⁹⁶ Alvarez, Luis and Chertow, Glenn, Real World In-Center Urea Clearance Experience with a Novel Hemodialysis System, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

¹⁹⁷ Chahal, Yaadveer. Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial, Abstract Accepted by the National Kidney Foundation Spring Clinical Meeting 2020.

¹⁹⁸ Outset Medical Data from Home IDE Trial, page 33 of clinical report submitted to the FDA, data Table 43, 2019.

Hemodialysis System. Although there are changes to the Tablo® Hemodialysis System for home use, the cartridge portion remains unchanged from its original FDA approval. Therefore, the cartridge itself is not new. Also, it is unclear as to whether the Tablo® Hemodialysis System can be used in-center without the cartridge. As such, much of the evidence presented in this application is really about the system itself, such as ease of training, its various features, and less about the incremental benefit of using the cartridge. Additionally, the system itself may have its own risks and benefits which are not within the scope of this application, and peripherally and incompletely addressed with the provided materials. For example, a study should be conducted determining the number of patients who were back in the hospital for a dialysis-related condition.

To evaluate the cartridge, it would be helpful to have studies on whether there are any issues with the components of the cartridge (that is, any dialyzer reactions to tubing, any issues affecting clearance). Since the primary intent of the cartridge is to facilitate patient set-up at home, the most useful evidence would be in the form of larger studies of patient-reported outcomes, quality of life, analyses of patient/caregiver burnout, and sustained adherence (beyond 1 year) to the use of this home-based modality. If the applicant is claiming to improve the patients' quality of life, then it needs to be proven for patient-specific outcomes and with a risk-benefit analysis to the patient. In some of the references cited, the patient factors affecting home HD are self-cannulation, burdens to caregivers, and concerns for complications, yet the cartridge has not demonstrated improvements in addressing these issues.

The cartridge is a promising concept to encourage home HD but again, the evaluation of this technology is complicated by the need to also peripherally assess the system. There does not appear to be a need for this cartridge in the hospital or clinic setting as trained personnel should

be able to assist with set-up. Within the larger policy context of FDA approval and the fact that TPNIES does not currently cover capital-related assets, the CMS TPNIES Work Group believes there are some irregularities and misalignments in the current application, and is concerned that the stand-alone cartridge cannot be evaluated for meeting the criteria for SCI.

We invite public comment as to whether the stand-alone cartridge of the Tablo[®] Hemodialysis System meets the SCI criteria for the TPNIES.

III. CY 2021 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 subsection (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 PPS 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 2021

1. CY 2021 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 the applicable annual market basket payment update, geographic 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.4.d of this proposed rule, the CY 2021 proposed ESRD PPS base rate is \$255.59, which reflects the application of the proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed addition to the ESRD PPS base rate to include calcimimetics, and the CY 2021 proposed ESRDB market basket increase of 2.2 percent reduced by the multifactor productivity adjustment of 0.4 percentage points, that is, 1.8 percent. Accordingly, we are proposing a CY 2021 per treatment payment rate of \$255.59 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.4.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 previously, we are proposing a CY 2021 AKI dialysis payment rate of \$255.59, adjusted by the ESRD facility's wage index.

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

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030),
- CY 2012 ESRD PPS final rule (76 FR 628),

- CY 2012 ESRD PPS final rule (76 FR 70228),
- CY 2013 ESRD PPS final rule (77 FR 67450),
- CY 2014 ESRD PPS final rule (78 FR 72156),
- CY 2015 ESRD PPS final rule (79 FR 66120),
- CY 2016 ESRD PPS final rule (80 FR 68968),
- CY 2017 ESRD PPS final rule (81 FR 77834),
- CY 2018 ESRD PPS final rule (82 FR 50738),
- CY 2019 ESRD PPS final rule (83 FR 56922), and
- CY 2020 ESRD PPS final rule (84 FR 60713).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposed Updates to Requirements Beginning with the PY 2023 ESRD QIP

1. PY 2023 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2023 ESRD QIP measure set will include the same 14 measures as the PY 2022 ESRD QIP measure set. These measures are described in Table 6.

TABLE 6: PY 2023 ESRD QIP Measure Set

National Quality Forum (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.

National Quality Forum (NQF) #	Measure Title and Description
Based on NQF #2979	Standardized Transfusion Ratio (STRR), a reporting measure 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 arteriovenous (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 (UFR), a reporting measure* Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (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 the Centers for Disease Control and Prevention (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

Note: We are proposing to update the scoring methodology used to calculate the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months.

2. Estimated Performance Standards for the PY 2023 ESRD QIP

Section 1881(h)(4)(A) of the Social Security Act (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 2020 ESRD PPS final rule (84 FR 60728), we set the performance period for the PY 2023 ESRD QIP as CY 2021 and the baseline period as CY 2019. In this proposed rule, we are estimating the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2023 clinical measures in Table 7 using data from 2018. We intend to update these standards, using CY 2019 data, in the CY 2021 ESRD PPS final rule.

TABLE 7: Estimated Performance Standards for the PY 2023 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 (VAT)			
Standardized Fistula Rate	53.72%	64.96%	77.31%
Catheter Rate	17.70%	10.50%	4.32%
Kt/V Comprehensive	93.56%	97.13%	99.24%
Hypercalcemia	1.77%	0.58% (0.59%)	0.00%
Standardized Readmission Ratio	1.268 (1.269)	0.998	0.629 (0.641)
Standardized Transfusion Ratio	1.675	0.830	0.173
NHSN BSI	1.365	0.604	0
Standardized Hospitalization Ratio	1.248	0.967 (0.976)	0.670 (0.677)
PPPW	8.12%	16.73%	33.90%
ICH CAHPS: Nephrologists’ Communication and Caring	58.12%	67.89%	78.52% (78.35%)
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16 (53.87%)	62.47%	72.11%
ICH CAHPS: Providing Information to Patients	74.09%	80.48%	87.14%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.92%)	62.22% (60.59%)	76.57% (75.16%)
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (48.59%)	63.04% (62.99%)	77.49%

ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.46%)	68.59%	83.03%
Note: If the PY 2023 final numerical value is worse than the PY 2022 finalized value, we will substitute the PY 2023 final numerical value for the PY 2022 finalized value. We have provided the PY 2023 finalized value as a reference in parentheses for clinical measures whose PY 2023 estimated value is worse than the PY 2022 finalized value.			

Data sources: VAT measures: 2018 CROWNWeb; SRR, SHR: 2018 Medicare claims; Kt/V: 2018 CROWNWeb; Hypercalcemia: 2018 CROWNWeb; NHSN: 2018 CDC; ICH CAHPS: CMS 2018; PPPW: 2018 CROWNWeb and 2018 OPTN.

3. Proposed Update to the Scoring Methodology for the Ultrafiltration Rate Reporting Measure

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77912). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. It is based upon the NQF-endorsed Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hr) (NQF #2701), which assesses the percentage of patient-months for patients with a UFR greater than or equal to 13 ml/kg/hr.

In the CY 2017 ESRD PPS final rule (81 FR 77917), we also finalized a policy to score the Ultrafiltration Rate reporting measure using the following equation, beginning in PY 2020 (81 FR 77917):

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

In this proposed rule, we are proposing to replace the current Ultrafiltration Rate reporting measure scoring equation with the following equation, beginning with PY 2023:

$$\left(\frac{\text{number of patient - months successfully reporting data}}{\text{number of eligible patient - months}} \times 12 \right) - 2$$

This proposal would modify the scoring methodology for the Ultrafiltration Rate reporting measure so that facilities would be scored based on the number of eligible patient-months, as opposed to facility-months. The facility-month scoring methodology requires

facilities to report every data element necessary to calculate a UFR reporting rate for 100 percent of its eligible patients each month in order to receive any credit for successfully reporting the measure for that month. The facility-month scoring approach then counts the number of months in the performance period that the facility received credit for reporting over the course of the performance period. For example, under the facility-scoring methodology, if a facility has 10 eligible patients in January, the facility must report all required UFR data elements for each of those 10 patients in order to receive any credit for January reporting. If the facility only reports the required UFR data elements for 9 of those 10 patients, the facility receives a zero for January. Our concern with this approach is that there may be circumstances, such as when an eligible patient is hospitalized, when facilities cannot obtain UFR data for a single patient, and as a consequence, cannot receive any credit for the data it did report that month. When we finalized the Ultrafiltration Rate reporting measure in the CY 2017 ESRD PPS final rule, stakeholders raised their concern regarding this issue (81 FR 77914). At the time, we responded that because we defined the population for this reporting measure by assignment to a facility for a full month, the facility is still required to provide data even in cases where a patient may spend part of that month hospitalized since the data elements are products of ongoing dialysis treatment. We stated that since we do not restrict facilities from coordinating with hospitals to obtain relevant data, we believed that such coordination is appropriate. However, our rationale for this was based on the reporting requirements prescribed by a facility-month definition. Furthermore, coordinating with hospitals to obtain relevant data continues to be a stakeholder concern in reporting UFR data. We believe that the proposed patient-month scoring methodology is more objective because it scores facilities based on the percentage of eligible patients across the entire performance period for which they report all UFR data elements. Thus, if a facility has 100 eligible patients in

CY 2020 and reports all data elements necessary to calculate a UFR rate for 90 of them, the facility will receive a rounded score based on a 90 percent reporting rate. We believe that this methodology will give facilities more flexibility to receive credit for UFR reporting throughout the 12-month performance period.

The Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing HD, because of indications that high ultrafiltration is an independent predictor of mortality. Faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. The outcome of this reporting measure is the documentation of the ultrafiltration measurements, which ultimately contributes to the quality of the patient's ESRD treatment. We believe that calculating the measure rates using the patient-month scoring methodology better supports our goal of assessing performance on whether the facility is documenting UFR for its eligible patients, which we believe will lead to better patient-level outcomes.

We also believe that this change is consistent with our plan to re-evaluate our reporting measures for opportunities to more closely align them with NQF measure specifications (see 84 FR 60724). We believe that this proposed change would make the Ultrafiltration Rate reporting measure more consistent with the NQF measure upon which it is based, Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hr) (NQF #2701), which reports results using a "patient-month" construction. Although we recognize that both the Anemia Management reporting measure and the Serum Phosphorus reporting measure are also calculated using a facility-month construction, we are not proposing to change the scoring methodology

used for either of those measures because both measures are finalized for removal beginning with the PY 2021 ESRD QIP (83 FR 56986 through 56989). The proposed update to the UFR reporting measure scoring methodology will make the scoring methodology for that measure consistent with the scoring methodology we are using to calculate the Medication Reconciliation (MedRec) reporting measure (83 FR 57011). We also believe that the utilization of this patient-month scoring methodology for both the MedRec and the Ultrafiltration Rate reporting measures better reflects our intent to score facilities based on actions taken by the facility that impact patient experiences. .

We seek comment on this proposal.

4. Eligibility Requirements for the PY 2023 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 8. We are not proposing any changes to these eligibility requirements for the PY 2023 ESRD QIP in this proposed rule.

TABLE 8: 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
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: 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	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)	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	Before October 1 prior to the performance period that applies to the program year.	N/A

	during the performance period		
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. Clarification of the Timeline for Facilities to Make Changes to Their NHSN Bloodstream Infection (BSI) Clinical Measure and NHSN Dialysis Event Reporting Measure Data for Purposes of the ESRD QIP

Under our current policy for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure, facilities are required to submit monthly data on a quarterly basis, and each quarter’s data is due 3 months after the end of the quarter (81 FR 77879 through 77881). For example, data collected by facilities between January 1 and March 31, 2021 is due to NHSN by June 30, 2021, data collected between April 1 and June 30, 2021 is due to NHSN by September 30, 2021, and data collected between July 1 and September 30, 2021 is due to NHSN by December 31, 2021. After each quarterly data submission deadline, the Centers for Disease Control and Prevention (CDC) takes a snapshot of the facility’s data for the quarter and creates a permanent data file. Each quarterly permanent data file is aggregated together to create the annual CMS ESRD QIP Final Compliance File, which the CDC transmits to CMS for purposes of determining whether the facility has met the reporting requirements for these measures. Facilities may make changes to their quarterly NHSN data for purposes of the ESRD QIP at any point up until the applicable quarterly submission data deadline.

We have become aware that the NHSN system does not prevent facilities from making

changes to their data for purposes of CDC surveillance after the applicable ESRD QIP quarterly submission deadline has passed. However, we are clarifying that any changes that a facility makes to its data after the ESRD QIP deadline that applies to those data will not be included in the quarterly permanent data file that the CDC generates for purposes of creating the annual CMS ESRD QIP Final Compliance File. Rather, as noted above, each quarterly permanent data file captures a snapshot of the facility's data as of the quarterly submission deadline, and that file cannot be updated for purposes of the ESRD QIP because of operational and timing issues.

6. Estimated Payment Reduction for the PY 2023 ESRD QIP

Under our current policy, a facility will not receive a payment reduction for a payment year in connection with its performance for the ESRD QIP if it achieves a total performance score (TPS) that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS 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.

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 2023, we estimate based on available data that a facility must meet or exceed a mTPS of 57 in order to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2018 instead of the PY 2023 baseline period (CY 2019) because CY 2019 data are not yet available.

We refer readers to Table 7 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 57 would receive a payment reduction based on the TPS ranges indicated in Table 9.

TABLE 9: Payment Reduction Scale for PY 2023 Based on the Most Recently Available Data

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

We intend to update the mTPS for PY 2023, as well as the payment reduction ranges for that payment year, in the CY 2021 ESRD PPS final rule.

7. Proposal to Reduce the Number of Records That a Facility Selected for NHSN Validation Must Submit

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 Consolidated Renal Operations in a Web-Enabled Network (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 2023 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. For additional information on this methodology, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767). In the CY 2020 ESRD PPS final rule, we finalized our proposal to continue using this methodology for the NHSN validation study for PY 2023 and subsequent years (84 FR 60727). In that rule, we 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, and that this sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on those results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP are accurate, we finalized our proposal to continue use of this methodology in the PY 2023 NHSN validation study and for subsequent years.

Additionally, as we had previously finalized for CROWNWeb validation, we finalized our proposal to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and are continuing 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.

In the CY 2019 ESRD PPS final rule, we finalized that a sample of 300 facilities will be selected for the NHSN validation study each year, and that each facility will be required to submit 20 patient records per quarter for each of the first two quarters of the calendar year (83 FR 57001), for a total of 40 records. In this proposed rule, we are proposing to change this requirement and allow facilities selected to participate in the NHSN validation study to submit a total of 20 patient records for the applicable calendar year. We are also proposing to allow

facilities to submit patient records from any two quarters during the year, as long as all of the records are from no more than two quarters. For example, a facility could choose to submit 2 records from Q1 and 18 records from Q4, or 6 records from Q2 and 14 records from Q3, but it could not submit 4 records from Q1, 8 records from Q2, and 8 records from Q3.

We have concluded that this revised approach would reduce facility burden by decreasing the required number of patient records and allowing more flexibility for facilities to choose what records to submit, while continuing to maintain a sample size that is adequate for our validation analysis. In reaching this conclusion, we were informed by the CDC's recommendations. Based on the sample estimation analysis, the CDC recommended the following factors to improve the precision of estimation of accuracy of dialysis events reported to NHSN: an expected 80 percent of dialysis events reporting accuracy from facilities and setting the precision of the NHSN validation study to a 95 percent confidence level and 1 percent margin of error, which would require a total of 6,072 chart reviews. Beginning with the CY 2017 and CY 2018 NHSN dialysis validation, we have gradually increased the number of facilities randomly selected for validation, as well as the number of charts for review, in order to achieve the 6,000 chart threshold necessary for an accurate review. Initially, 35 facilities were randomly selected and 10 charts per facility were reviewed. For CY 2019, 150 facilities were randomly selected and each facility submitted a total of 20 records, to achieve the total of 3,000 charts available for review. For CY 2020, the goal was to increase from 150 to 300 facilities, where each facility would submit a total of 20 records thereby achieving the total of 6,000 charts available for review, as we previously finalized (83 FR 57001). Because a total of 20 records would achieve the 6,000 chart threshold necessary for an accurate review, we concluded that we could reduce the sample size from 40 records to 20 records. We believe a total of 20 medical records across a 6-month

validation study time frame for a calendar year, rather than 20 records per quarter, would provide a sufficiently accurate sample size.

We believe the reduction in patient records still provides an adequate sample size for the validation and reduces overall facility burden. A recent estimation analysis conducted by the CDC supports our belief that a review of 20 charts per facility across a specified validation timeline that are acquired by randomly selecting approximately 300 facilities would continue to meet the medical record selection criteria outlined in the NHSN Dialysis Validation methodology. This would meet the CDC's recommended sample estimate to achieve the 95 percent confidence level precision and 1 percent margin of error, while also reducing facility burden.

We seek comment on this proposal.

We are not proposing any changes to the CROWNWeb validation study methodology.

C. Proposals for the PY 2024 ESRD QIP

1. Continuing Measures for the PY 2024 ESRD QIP

Under our previously adopted policy, the PY 2023 ESRD QIP measure set will also be used for PY 2024.

2. 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. In the CY 2020 ESRD PPS final rule, we finalized the performance and baseline periods for the PY 2023 ESRD QIP (84 FR 60728). We also finalized our proposal 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 and CY 2020 as the baseline period for the PY 2024 ESRD QIP.

In this proposed rule, we are not proposing any changes to this policy.

3. Performance Standards for the PY 2024 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 2012 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 2024 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 2020 data. We intend to publish these numerical values, using CY 2020 data, in the CY 2022 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2024 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 2024.

4. Scoring the PY 2024 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(e).

We are not proposing to change our scoring policies in this proposed rule.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the Ultrafiltration Rate reporting measure, MedRec reporting measure, and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STrR reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). We refer the reader to section IV.B.3 of this proposed rule for proposed changes to the scoring methodology for the Ultrafiltration Rate reporting measure.

5. Weighting the Measure Domains and the TPS for PY 2024

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and

the Safety Measure domain a weight of 15 percent of the TPS.

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 (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729). We are not proposing any updates to these policies. 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. 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, the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

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

B. Requirements in Regulation Text

In sections II.B.1 through II.B.3 and II.B.5 of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS for CY 2021. 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 2019 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 median hourly wage of a Medical Records and Health

Information Technician is \$20.50 per hour.¹⁹⁹ Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of \$41.00 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2023 that we discussed in the CY 2020 ESRD QIP final rule (84 FR 60787 through 60788) and to estimate the total information collection burden in the ESRD QIP for PY 2024. We provide the re-estimated information collection burden associated with the PY 2023 ESRD QIP and the newly estimated information collection burden associated with the PY 2024 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 2023 and PY 2024

In the CY 2020 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 are selected each

¹⁹⁹ <https://www.bls.gov/oes/current/oes292098.htm>.

year to submit 10 records to CMS, and we 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. In this proposed rule, we are updating these estimates using a newly available wage estimate of a Medical Records and Health Information Technician. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately \$30,750 (750 hours x \$41.00), or an annual total of approximately \$102.50 (\$30,750/300 facilities) per facility in the sample. The decrease in our burden estimate is due to using the median hourly wage instead of the mean hourly wage 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 proposed to reduce the number of records that a facility selected to participate in the NHSN data validation study must submit to a CMS contractor, beginning with PY 2023. Under the proposal, a facility would be required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this proposal is the time and effort necessary to submit the requested records to a CMS contractor. Applying our proposal to reduce the number of records required from each facility participating in the NHSN validation study, we

estimate that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are asked to submit records each year, we estimate that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities x 5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that the aggregate cost of the NHSN data validation each year would be approximately \$61,500 (1,500 hours × \$41), or a total of approximately \$205 (\$61,500/300 facilities) per facility in the sample. The reduction in our burden estimate is due to a reduction in the number of medical records collected and the utilization of the median hourly wage instead of the mean hourly wage. The burden associated with these requirements is captured in an information collection request (OMB control number 0938-1340).

3. CROWNWeb Reporting Requirements for PY 2023 and PY 2024

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 2020 ESRD PPS final rule, we estimated that the burden associated CROWNWeb reporting requirements for the PY 2023 ESRD QIP was approximately \$211 million.

We are not proposing any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2023 or PY 2024. However, we have re-calculated the burden estimate for PY 2023 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 2020 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. There are 229 data elements for 523,314 patients across 7,386 facilities. At 2.5 minutes per element, this yields approximately 676.05 hours per facility. Therefore, the PY 2023 burden is 4,993,288 hours (676.05 hours x 7,386 facilities). (Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2023 total burden cost is \$205 million (4,993,288 hours x \$41). There is no net incremental burden change from PY 2023 to PY 2024 because we are not proposing to change the reporting requirements for PY 2024.

VI. 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.

VII. 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, Executive Order 13563 on Improving Regulation and Regulatory Review, the Regulatory Flexibility Act (RFA) (Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, the Congressional Review Act (5 U.S.C. 801 et seq.), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs.

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 for CY 2021. The proposed routine updates include the CY 2021 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 2021 for renal dialysis services furnished to ESRD beneficiaries.

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 2021 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule proposes to implement requirements for the ESRD QIP, including a proposal to modify the scoring methodology for the Ultrafiltration Rate reporting measure beginning with the PY 2023 ESRD QIP and a proposal to update the reporting requirements for facilities selected for NHSN data validation. The rule also clarifies the review and correction timeline for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure.

3. Overall Impact

a. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$190 million in payments to ESRD facilities in CY 2021, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, the proposal to adopt the new OMB delineations with a transition period, and the proposal to include calcimimetics in the ESRD PPS base rate. These figures do not reflect estimated increases or decreases in expenditures based on our proposal to expand eligibility for the TPNIES to certain new and innovative home dialysis machines when used in the home. The fiscal impact of this proposal cannot be determined due to the uniqueness of each new and innovative home dialysis machine and its cost.

b. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately \$5 million in payments to ESRD facilities in CY 2021.

c. ESRD QIP

For PY 2023, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP 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 changes to our methodology for calculating the annual burden associated with the information collection requirements for the CROWNWeb validation study and CROWNWeb reporting. We updated the annual burden associated with the NHSN validation study to reflect our proposal to reduce the total number of records collected. This proposed update would reduce the collection of information requirements associated with the NHSN validation study by \$65,460 per year across the facilities

selected for validation that year.

We also updated the payment reduction estimates using more recent data for the measures in the ESRD QIP measure set and applying our proposal to modify the scoring methodology for the Ultrafiltration Rate reporting measure beginning with the PY 2023 ESRD QIP. We estimate \$205 million in information collection burden, which includes the cost of complying with this rule, and an additional \$16 million in estimated payment reductions across all facilities for PY 2023.

For PY 2024, we estimate that the proposed revisions to the ESRD QIP would result in \$205 million in information collection burden and \$16 million in estimated payment reductions across all facilities impact of \$221 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule.

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) for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$109.36 per hour, including overhead and fringe benefits

https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is \$683.50 (6.25 hours x \$109.36).

Therefore, we estimate that the total cost of reviewing this regulation rounds to \$62,882.

(\$683.50 x 92 reviewers).

B. Detailed Economic Analysis

1. CY 2021 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 2020 to estimated payments in CY 2021. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2020 and CY 2021 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 2019 data from the Part A and Part B Common Working Files as of April 3, 2020, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2019 claims to 2020 and 2021 using various updates.

The updates to the ESRD PPS base rate are described in section II.B.4.d of this proposed rule.

Table 10 shows the impact of the estimated CY 2021 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2020.

TABLE 10: Impact of Proposed Changes in Payment to ESRD Facilities for CY 2021 Proposed Rule

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Effect of 2021 Changes in Outlier Policy (C)	Effect of Changes in Wage Index Data (D)	Effect of CBSA change & 5% Cap Policy (E)	Effect of Bundling Calcimimetics into Base Rate (F)	Effect of Change for Payment Rate Update (G)	Effect of Total 2021 Proposed Changes (H)
All Facilities	7,610	44.8	0.3%	0.0%	0.0%	-0.6%	1.8%	1.6%
Type								
Freestanding	7,224	43.1	0.3%	0.0%	0.0%	-0.5%	1.8%	1.6%
Hospital based	386	1.8	0.6%	0.1%	0.1%	-2.9%	1.8%	-0.4%
Ownership Type								
Large dialysis organization	5,809	34.8	0.3%	0.0%	0.0%	0.3%	1.8%	2.4%
Regional chain	944	5.7	0.2%	0.0%	-0.1%	-3.9%	1.8%	-2.0%
Independent	534	2.9	0.3%	0.1%	0.3%	-2.5%	1.8%	0.0%
Hospital based ¹	299	1.3	0.6%	0.1%	0.2%	-2.5%	1.8%	0.1%
Unknown	24	0.0	0.6%	-0.7%	-0.1%	1.5%	1.8%	3.1%
Geographic Location ^{2,3}								
Rural	1,292	6.5	0.3%	0.1%	-1.2%	-0.5%	1.8%	0.6%
Urban	6,318	38.4	0.3%	0.0%	0.2%	-0.6%	1.8%	1.7%
Census Region								
East North Central	1,220	6.0	0.4%	0.0%	-0.1%	0.0%	1.8%	2.1%
East South Central	604	3.3	0.3%	0.0%	0.0%	-1.7%	1.8%	0.3%
Middle Atlantic	845	5.4	0.4%	0.4%	0.3%	-1.2%	1.8%	1.6%
Mountain	419	2.4	0.2%	-0.4%	-0.1%	0.9%	1.8%	2.5%
New England	201	1.4	0.3%	-0.8%	-0.1%	-0.2%	1.8%	1.0%
Pacific ⁴	907	6.4	0.3%	0.0%	0.1%	0.5%	1.8%	2.6%
Puerto Rico and Virgin Islands	52	0.3	0.2%	0.0%	-0.1%	0.2%	1.8%	2.1%
South Atlantic	1,746	10.7	0.4%	0.1%	0.0%	-1.3%	1.8%	0.8%
West North Central	514	2.3	0.4%	-0.3%	-0.1%	0.2%	1.8%	2.1%
West South Central	1,102	6.7	0.3%	0.1%	0.0%	-0.9%	1.8%	1.2%
Facility Size								

Less than 4,000 treatments	1,315	2.6	0.3%	0.0%	0.0%	0.6%	1.8%	2.7%
4,000 to 9,999 treatments	2,803	12.2	0.3%	0.0%	-0.1%	-0.5%	1.8%	1.6%
10,000 or more treatments	3,246	29.7	0.3%	0.0%	0.0%	-0.7%	1.8%	1.4%
Unknown	246	0.3	0.3%	-0.2%	0.1%	-0.1%	1.8%	1.9%
Percentage of Pediatric Patients								
Less than 2%	7,508	44.5	0.3%	0.0%	0.0%	-0.6%	1.8%	1.5%
Between 2% and 19%	36	0.3	0.3%	0.2%	-0.1%	-0.9%	1.8%	1.3%
Between 20% and 49%	13	0.0	0.3%	-0.1%	-0.1%	3.9%	1.8%	5.8%
More than 50%	53	0.0	0.2%	0.0%	-0.1%	4.5%	1.8%	6.5%

¹Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

²Facility counts for Urban/Rural uses 2021 CBSA delineation. Under 2020 and previous CBSA delineation, facility counts for urban and rural are 6,306 and 1,304 respectively. For payment percent change columns, appropriate definition of Urban/Rural is used for each step.

³The 1.17 percent drop in total payments among rural facilities (and increase in total payments among urban facilities) is mostly due facilities shifting from rural to urban status under new CBSA delineation. Controlling for old-CBSA urban/rural status, the change in payment is close to 0 percent.

⁴Includes 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.4.c of this proposed rule is shown in column C. For CY 2021, 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. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2021 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the annual update to the wage index, as described in section II.B.4.b of this proposed rule. That is, this column reflects the update from the CY 2020 ESRD PPS wage index using CY 2020 OMB delineations with a basis of the FY 2021 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. The total impact of this change is 0.0 percent, however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show

changes in estimated payments ranging from a 0.8 percent decrease to a 0.4 percent increase due to the annual update to the ESRD PPS wage index.

Column E shows the effect of adopting the proposed new OMB delineations and the transition policy as described in sections II.B.4.b.(2) and II.B.4.b.(3), respectively, of this proposed rule. That is, the impact represented in this column reflects the change from using the CY 2020 OMB delineations and basing the CY 2021 ESRD PPS wage index on the FY 2021 pre-floor, pre-reclassified IPPS hospital wage index data to the new OMB delineations and a 5 percent cap on wage index decreases in CY 2021, in a budget neutral manner. The total impact of this change is 0.0 percent, however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 1.2 percent decrease to a 0.3 percent increase due to these proposals to the ESRD PPS wage index.

Column F shows the effect of the proposed addition to the ESRD PPS base rate to include calcimimetics as described in section II.B.1 of this proposed rule. That is, the impact represented in this column reflects the change, under the ESRD PPS, proposed for payment to ESRD facilities for furnishing calcimimetics. Beginning January 1, 2018, ESRD facilities received payment for calcimimetics under the TDAPA policy in § 413.234(c). Under our proposal, beginning January 1, 2021, we would modify the ESRD PPS base rate by adding \$12.06 to include calcimimetics and no longer pay for calcimimetics using the TDAPA. In addition, calcimimetics would become outlier eligible services under § 413.237. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 3.9 percent decrease to a 4.5 percent increase due to this proposal.

Column G shows the effect of the proposed CY 2021 ESRD PPS payment rate update as

described in section II.B.4.a of this proposed rule. The proposed ESRD PPS payment rate update is 1.8 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2021 of 2.2 percent and the proposed MFP adjustment of 0.4 percent.

Column H reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed updated wage index and transition policy, the payment rate update, and the proposed addition to the ESRD PPS base rate to include calcimimetics. We expect that overall ESRD facilities would experience a 1.6 percent increase in estimated payments in CY 2021. The categories of types of facilities in the impact table show impacts ranging from a 2.0 percent decrease to a 6.5 percent increase in their CY 2021 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 2021, 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 2021 would be approximately \$9.3 billion. This estimate takes into account a projected decrease in fee-for-service Medicare dialysis beneficiary enrollment of 8.6 percent in CY 2021.

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 2021 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2021, which translates to approximately \$40 million.

e. Alternatives Considered

(1) Inclusion of Calcimimetics into the ESRD PPS Bundled Payment

In section II.B.1 of this proposed rule, we propose that beginning January 1, 2021, we would modify the ESRD PPS base rate by adding \$12.06 to include calcimimetics and no longer pay for calcimimetics using the TDAPA. In addition, calcimimetics would become ESRD outlier services eligible for outlier payments under § 413.237. With regard to the methodology proposed to calculate the amount to be added the ESRD PPS base rate, we considered using the Medicare expenditures reflecting payments made for the calcimimetics in CYs 2018 and 2019, that is, approximately \$2.3 billion and dividing by total treatments furnished in both years to arrive at an amount of \$27.08. However, using the most recent calendar quarter of ASP data available to calculate the ASP-based values as the proxy rate incorporates the lower priced generic calcimimetics into the calculation of the amount added for oral calcimimetics. We believe it is appropriate for the ESRD PPS base rate to reflect generic drug manufacturer ASP data since we believe that this aligns with how ESRD facilities would purchase and furnish the oral calcimimetics in the future.

(2) Expansion of the TPNIES to Capital-Related Assets that are Home Dialysis Machines When Used in the Home for a Single Patient

In section II.B.3 of this proposed rule, we propose to expand the TPNIES policy and allow capital-related assets that are home dialysis machines when used in the home for a single patient to be eligible for the add-on payment adjustment when used in the home. Then,

consistent with the policies finalized last year for other renal dialysis equipment and supplies eligible for the TPNIES, we would pay 65 percent of the pre-adjusted per treatment amount for a period of 2 years. With regard to the duration of applying the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient, we considered paying the TPNIES for 3 years. However, we believe that the proposal is consistent with the TDAPA and other Medicare fee-for-service add-on payment programs (for example, the IPPS NTAP), and supports innovation for dialysis in the home setting, the President's Executive Order on Advancing American Kidney Health, and current HHS initiatives to support home dialysis, while taking into account the potential increase in ESRD PPS expenditures.

(3) CY 2021 ESRD PPS Wage index

In section II.B.4.b of this proposed rule, we propose to adopt the new OMB delineations with a transition policy. That is, we are proposing to adopt the OMB delineations based on the September 14, 2018 OMB Bulletin No. 18-04 and, to mitigate any potential negative impacts, we would apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would be phased in over 2 years, such that the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021 and no cap would be applied to the reduction in the wage index for the second year, CY 2022. With regard to the transition policy, we considered doing a 2-year 50/50 blended wage index approach consistent with the adoption of OMB delineations in the CY 2015 ESRD PPS final rule (79 FR 66142). However, we determined that the proposed 5 percent cap on any decrease policy would be an appropriate transition for CY 2021 as it provides predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than the 50/50 blended approach.

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 2020 to estimated payments in CY 2021. 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 2020 and CY 2021 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 2019 data from the Part A and Part B Common Working Files as of April 3, 2020, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2019 claims to 2020 and 2021 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 11 shows the impact of the estimated CY 2021 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 2020.

TABLE 11: Impact of Proposed Changes in Payment for Renal Dialysis Services Furnished to Individuals with AKI for CY 2021 Proposed Rule

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of All Wage Index Changes (C)	Effect of Bundling Calcimimetics in the Base Rate (D)	Effect of Changes in Payment Rate Update (E)	Effect of Total 2021 Proposed Changes (F)
All Facilities	5,064	284.9	-0.1%	5.0%	1.8%	6.9%
Type						
Freestanding	4,941	279.6	-0.1%	5.0%	1.8%	6.9%
Hospital based	123	5.3	0.0%	5.0%	1.8%	6.9%
Ownership Type						
Large dialysis organization	4,189	239.5	-0.1%	5.0%	1.8%	6.9%
Regional chain	583	29.2	-0.1%	5.0%	1.8%	6.8%
Independent	208	12.8	0.1%	5.0%	1.8%	7.0%
Hospital based ¹	77	3.3	0.2%	5.0%	1.8%	7.1%
Unknown	7	0.1	-0.9%	5.0%	1.8%	6.0%
Geographic Location²						
Rural	874	45.1	-0.2%	5.0%	1.8%	6.7%
Urban	4,190	239.8	0.0%	5.0%	1.8%	6.9%
Census Region						
East North Central	886	52.8	-0.1%	5.0%	1.8%	6.9%
East South Central	404	20.4	-0.2%	5.0%	1.8%	6.7%
Middle Atlantic	518	31.7	0.3%	5.0%	1.8%	7.3%
Mountain	291	16.8	-0.4%	5.0%	1.8%	6.5%
New England	157	8.3	-1.0%	5.0%	1.8%	5.9%
Pacific ³	596	43.4	0.0%	5.0%	1.8%	6.9%
Puerto Rico and Virgin Islands	2	0.0	-0.1%	5.0%	1.8%	6.8%
South Atlantic	1,190	66.0	0.0%	5.0%	1.8%	6.9%
West North Central	349	13.7	-0.5%	5.0%	1.8%	6.4%
West South Central	671	31.8	0.1%	5.0%	1.8%	7.0%
Facility Size						
Less than 4,000 treatments	652	27.7	-0.1%	5.0%	1.8%	6.8%
4,000 to 9,999 treatments	1,915	99.0	-0.1%	5.0%	1.8%	6.9%
10,000 or more treatments	2,398	154.7	-0.1%	5.0%	1.8%	6.9%
Unknown	99	3.4	0.0%	5.0%	1.8%	6.9%
Percentage of Pediatric Patients						
Less than 2%	5,064	284.9	-0.1%	5.0%	1.8%	6.9%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%	0.0%

More than 50%	0	0.0	0.0%	0.0%	0.0%	0.0%
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¹Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

²Facility counts for Urban/Rural uses 2021 CBSA delineation. Under 2020 and previous CBSA delineation, facility counts for urban and rural are 4,180 and 884 respectively. For payment percent change columns, appropriate definition of Urban/Rural is used for each step.

³Includes 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 2021 wage indices.

Column D shows the effect of the adjustment to the AKI dialysis payment rate that reciprocates the adjustment proposed to the ESRD PPS base rate for CY 2021, consistent with § 413.372. As discussed in section II.B.1 of this proposed rule, we propose to modify the ESRD PPS base rate by adding \$12.06 to include calcimimetics.

Column E shows the effect of the proposed CY 2021 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.8 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2021 of 2.2 percent and the proposed MFP adjustment of 0.4 percent.

Column F reflects the overall impact, that is, the effects of the updated wage index, the proposed addition to the ESRD PPS base rate, and the payment rate update. We expect that overall ESRD facilities would experience a 6.9 percent increase in estimated payments in CY 2021. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 7.3 percent in their CY 2021 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we propose 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 \$56 million would be paid to ESRD facilities in CY 2021 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 2023 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. The general methodology that we are using to determine a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2023 ESRD QIP would apply to the ESRD PPS payments made to the facility for services furnished in CY 2023, as codified in our regulations at § 413.177.

For the PY 2023 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 23.2 percent or 1,657 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. We are presenting an estimate for the PY 2023 ESRD QIP to update the estimated impact that was provided in the CY 2020 ESRD PPS final rule (84 FR 60797). If our proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure is finalized, the total estimated payment reductions for all the 1,657 facilities expected to receive a payment reduction in PY 2023 would decrease from \$18,247,083.76 to approximately \$15,586,453.64. Facilities that do not receive a TPS do not receive a payment reduction.

Table 12 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 12: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,490	76.82%
0.5%	1,215	17.00%
1.0%	336	4.70%
1.5%	65	0.91%
2.0%	41	0.57%

*239 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for 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 13) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 13. These estimates also incorporate the proposed update to the scoring methodology for the Ultrafiltration Rate reporting measure.

TABLE 13: Data Used to Estimate PY 2023 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SHR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT		
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
% Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR and SRR, clinical measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to

have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposals outlined in sections 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 2018 and December 2018 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 14 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2023. The table also 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 2023 ESRD QIP, the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided here.

TABLE 14: Estimated Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2023

	Number of Facilities	Number of Treatments 2018 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,386	44.6	7,147	1,657	-0.15%
Facility Type:					
Freestanding	6,995	42.7	6,791	1,556	-0.15%
Hospital-based	391	1.9	356	101	-0.22%
Ownership Type:					
Large Dialysis	5,603	34.5	5,473	1,115	-0.12%
Regional Chain	927	5.7	897	241	-0.19%
Independent	512	2.9	488	216	-0.34%
Hospital-based (non-chain)	305	1.5	275	83	-0.24%
Unknown	39	0.0	14	2	-0.10%
Facility Size:					
Large Entities	6,530	40.2	6,370	1,356	-0.13%
Small Entities ¹	817	4.4	763	299	-0.30%
Unknown	39	0.0	14	2	-0.10%
Rural Status:					
1) Yes	1,285	6.5	1,239	138	-0.06%
2) No	6,101	38.2	5,908	1,519	-0.17%
Census Region:					
Northeast	1,004	6.9	974	213	-0.13%
Midwest	1,696	8.4	1,634	393	-0.16%
South	3,360	20.4	3,232	823	-0.16%
West	1,271	8.6	1,252	180	-0.08%
US Territories ²	55	0.4	55	48	-1.36%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,140	315	-0.19%
East South Central	587	3.3	578	131	-0.14%
Middle Atlantic	806	5.4	779	190	-0.15%
Mountain	409	2.3	404	52	-0.08%
New England	198	1.4	195	23	-0.06%
Pacific	862	6.3	848	128	-0.08%
South Atlantic	1,699	10.5	1,642	475	-0.19%
West North Central	508	2.2	494	78	-0.09%
West South Central	1,074	6.6	1,012	217	-0.13%
US Territories ²	47	0.3	47	46	-1.57%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,114	220	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	488	-0.11%
Over 10,000 treatments	3,159	29.8	3,149	882	-0.18%
Unknown	377	0.5	264	67	-0.22%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

²Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

b. Effects of the PY 2024 ESRD QIP on ESRD Facilities

For the PY 2024 ESRD QIP, we estimate that, of the 7,386 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 23.2 percent or 1,657 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2024. The total payment reductions for all the 1,657 facilities expected to receive a payment reduction is approximately \$15,586,453.64. Facilities that do not receive a TPS do not receive a payment reduction.

Table 15 shows the overall estimated distribution of payment reductions resulting from the PY 2024 ESRD QIP.

TABLE 15: Estimated Distribution of PY 2024 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,490	76.82%
0.5%	1,215	17.00%
1.0%	336	4.70%
1.5%	65	0.91%
2.0%	41	0.57%

*239 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2024, 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 were calculated using the most recent data available (specified in Table 15) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 16.

TABLE 16: Data Used to Estimate PY 2024 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2017-Dec 2017	Jan 2018-Dec 2018
SRR	Jan 2017-Dec 2017	Jan 2018-Dec 2018

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
SHR	Jan 2017-Dec 2017	Jan 2018-Dec 2018
PPPW	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Kt/V Dialysis Adequacy Comprehensive	Jan 2017-Dec 2017	Jan 2018-Dec 2018
VAT		
Standardized Fistula Ratio	Jan 2017-Dec 2017	Jan 2018-Dec 2018
% Catheter	Jan 2017-Dec 2017	Jan 2018-Dec 2018
Hypercalcemia	Jan 2017-Dec 2017	Jan 2018-Dec 2018

For all measures except SHR, SRR, and STrR, measures with less than 11 patients for a facility were not included in that facility’s TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility’s TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility’s TPS. Each facility’s TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates 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 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 2024 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2018 and December 2018 by the facility’s estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 17 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2024. 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 2024 ESRD QIP, the actual impact of the PY 2024 ESRD QIP may vary significantly from the values provided here.

TABLE 17: Estimated Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2024

	Number of Facilities	Number of Treatments 2018 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,386	44.6	7,147	1,657	-0.15%
Facility Type:					
Freestanding	6,995	42.7	6,791	1,556	-0.15%
Hospital-based	391	1.9	356	101	-0.22%
Ownership Type:					
Large Dialysis	5,603	34.5	5,473	1,115	-0.12%
Regional Chain	927	5.7	897	241	-0.19%
Independent	512	2.9	488	216	-0.34%
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Unknown	39	0.0	14	2	-0.10%
Facility Size:					
Large Entities	6,530	40.2	6,370	1,356	-0.13%
Small Entities ¹	817	4.4	763	299	-0.30%
Unknown	39	0.0	14	2	-0.10%
Rural Status:					
1) Yes	1,285	6.5	1,239	138	-0.06%
2) No	6,101	38.2	5,908	1,519	-0.17%
Census Region:					
Northeast	1,004	6.9	974	213	-0.13%
Midwest	1,696	8.4	1,634	393	-0.16%
South	3,360	20.4	3,232	823	-0.16%
West	1,271	8.6	1,252	180	-0.08%
US Territories ²	55	0.4	55	48	-1.36%
Census Division:					
Unknown	8	0.1	8	2	-0.12%
East North Central	1,188	6.1	1,140	315	-0.19%
East South Central	587	3.3	578	131	-0.14%
Middle Atlantic	806	5.4	779	190	-0.15%
Mountain	409	2.3	404	52	-0.08%
New England	198	1.4	195	23	-0.06%
Pacific	862	6.3	848	128	-0.08%
South Atlantic	1,699	10.5	1,642	475	-0.19%
West North Central	508	2.2	494	78	-0.09%
West South Central	1,074	6.6	1,012	217	-0.13%
US Territories ²	47	0.3	47	46	-1.57%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,206	2.5	1,114	220	-0.15%
4,000-9,999 treatments	2,644	11.9	2,620	488	-0.11%
Over 10,000 treatments	3,159	29.8	3,149	882	-0.18%
Unknown	377	0.5	264	67	-0.22%

¹Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

²Includes 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 2024, we estimate that the ESRD QIP would contribute approximately \$15,586,453.64 in Medicare savings. For comparison, Table 18 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2024.

TABLE 18: Estimated Payment Reductions Payment Years 2018 through 2024

Payment year	Estimated payment reductions
PY 2024	\$15,586,453.64
PY 2023	\$15,586,453.64
PY 2022	\$18,247,083.76 (84 FR 60794)
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 section IV.B.7 of this proposed rule, we are proposing that facilities selected to participate in the NHSN data validation study can submit a total of 20 records across two quarters. We considered retaining our current reporting requirement, under which facilities must submit 20 records per quarter for each of the first two quarters of the CY, for a total of 40 records. However, we concluded that the reduction in patient records provides an adequate sample size for the validation. This approach would lower administrative costs and would reduce the burden on facilities.

C. Accounting Statement

As required by OMB Circular A-4 (available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in Table 19, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 19: Accounting Statement: Classification of Estimated Transfers and Costs/Savings ESRD PPS and AKI (CY 2021)	
Category	Transfers
Annualized Monetized Transfers	\$150 million
From Whom to Whom	Federal government to ESRD providers
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$40 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2023	
Category	Transfers
Annualized Monetized Transfers	-\$16 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2024	
Category	Transfers
Annualized Monetized Transfers	-\$16 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 (RFA)

The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration’s (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than \$41.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA’s size standards, see the Small Business Administration’s Web site at <http://www.sba.gov/content/small-business-size-standards> (Kidney Dialysis Centers are listed as 621492 with a size standard of \$41.5 million).

We do not believe ESRD facilities are operated by small government entities such as

counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 10. Using the definitions in this ownership category, we consider 534 facilities that are independent and 299 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than \$41.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates 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 0.1 percent increase in payments for CY 2021. An independent facility (as defined by ownership type) is estimated to have no change in payments for CY 2021.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for \$56 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,657 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2024 ESRD QIP, 817 are ESRD small entity facilities. We present these findings in Table 15 (“Estimated Distribution of PY 2024 ESRD QIP Payment Reductions”) and Table 17 (“Impact of Proposed QIP Payment

Reductions to ESRD Facilities for PY 2024”). We estimate that the payment reductions would average approximately \$9,406.43 per facility across the 1,657 facilities receiving a payment reduction, and \$8,698.69 for each small entity facility. We also estimate that there are 817 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.30 percent in CY 2022.

Therefore, the Secretary has determined that this proposed rule 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 RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 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 127 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 127 rural hospital-based dialysis facilities would experience an estimated 0.3 percent decrease in payments.

Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This proposed rule does not mandate any requirements for state, local, or tribal governments in the aggregate, or by the private sector. 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

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. We have reviewed this proposed rule 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. Regulatory Reform Analysis under Executive Order 13771

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.

VIII. 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 in 42 CFR Part 413

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

2. Section 413.232 is amended by—

- a. Revising paragraphs (b) introductory text, (b)(1), (e), and (g) introductory text; and
- b. Adding paragraphs (g)(4) and (h).

The revisions and additions read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) preceding the payment year; and

* * * * *

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must

provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section, except that:

- (1) For payment year 2012, the attestation must be provided by January 3, 2012;
- (2) For payment year 2015, the attestation must be provided by December 31, 2014;
- (3) For payment year 2016, the attestation must be provided by December 31, 2015; and
- (4) For payment year 2021, the attestation must be provided by December 31, 2020.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in their attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraph (g)(4) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(4) For payment years 2021, 2022, and 2023, the attestation specified in paragraph (e)(4) of this section must indicate that the ESRD facility meets all the criteria specified in this section, except that, for a facility that would not otherwise meet the number of treatments criterion specified in paragraph (b)(1) of this section because of the COVID-19 PHE, the facility may attest that it furnished less than 2,000 treatments in any six months during the cost-reporting period ending in 2020. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the payment year due to temporary patient shifting as a result of the COVID-19 PHE; and

(ii) The MAC relies on the attestation and multiplies the total number of treatments for the 6 months period by 2.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

3. Section 413.234 is amended by adding paragraph (f) to read as follows:

§ 413.234. Drug designation process.

* * * * *

(f) *Methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics in the ESRD PPS bundled payment.* Beginning January 1, 2021, payment for calcimimetics are included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (f)(2) of this section for determining the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for calendar years 2018 and 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in calendar years 2018 and 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

4. Section 413.236 is amended by—

a. Revising paragraphs (a), (b) introductory text, (b)(2), (4) through (6), (c), (d)

introductory text, and (d)(2); and

b. Adding paragraph (f).

The revisions and addition read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety, meaning that one new part of a machine does not make the entire capital-related asset new, that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual

allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

* * * * *

(2) Is new, meaning within 3 years beginning on the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or

equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website 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. For capital-related assets that are home dialysis machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

* * * * *

(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, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

* * * * *

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-

related asset that is a home dialysis machine, as defined in paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year for use in calculating the pre-adjusted per treatment amount, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(2) [Reserved]

5. Section 413.237 is amended—

a. In paragraphs (a)(1)(i) through (iii) by removing the semicolon at the end of the sentence and adding a period in its place;

b. In paragraph (a)(1)(iv) by removing “; and” and adding a period in its place; and

c. By revising paragraph (a)(1)(v).

The revision reads as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236, after the payment period has ended.

* * * * *

Dated: June 12, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: June 19, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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