DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1768–P]

RIN 0938–AU79

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, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2023. This proposed rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also includes requests for information regarding potential payment adjustments for certain new renal dialysis drugs and biological products as well as health equity issues under the ESRD PPS with a focus on pediatric dialysis payment. In addition, this proposed rule proposes to update requirements for the ESRD Quality Incentive Program. Finally, this proposed rule would make updates to the ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 22, 2022.

ADDRESSES: In commenting, please refer to file code CMS–1768–P.

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–1768–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–1768–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.

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) or the Transitional Drug Add-on Payment Adjustment (TDAPA).

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

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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I. Executive Summary

A. Purpose

This rule proposes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute

kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

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 proposed rule would update the ESRD PPS for CY 2023.

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 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 proposed rule would update the AKI payment rate for CY 2023.

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 facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This proposed rule proposes several updates for Payment Year (PY) 2023, including the suppression of individual ESRD QIP measures for PY 2023 under the measure suppression policy previously finalized for the duration of the COVID–19 public health emergency (PHE), as well as updates for PY 2024 and PY 2025. At this time, no new requirements are being proposed beginning with the PY 2026 ESRD QIP.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled, ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' This proposed rule would make certain changes to the ETC Model, including adding a parameter to the Performance Payment Adjustment (PPA) achievement scoring methodology and adding an additional protection related to flexibilities for furnishing and billing kidney disease patient education services by ETC Participants. This proposed rule also discusses our intent to disseminate participant-level model performance information to the public.

B. Summary of the Major Provisions

1. ESRD PPS

- *Rebasing and revision of the End-Stage Renal Disease Bundled (ESRDB) market basket for CY 2023:* We are proposing to rebase and revise the ESRDB market basket to a 2020 base year, reflecting the most recent and complete set of Medicare Cost Report data as well as other publicly available data. In addition, we are proposing to update the labor-related share of the ESRD PPS base rate to reflect the proposed 2020 labor-related cost share weights designated in the ESRDB market basket.
- *Update to the ESRD PPS base rate for CY 2023:* The proposed CY 2023 ESRD PPS base rate is $264.09. This proposed amount reflects the application of the wage index budget-neutrality adjustment factor (0.999997) and a proposed productivity-adjusted market basket increase of 2.4 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $264.09 (($257.90 × 0.999997) × 1.024 = $264.09).
- *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 2023, we are proposing to update the wage index values based on the latest available data.
- *Permanent cap on wage index decreases:* For CY 2023 and subsequent years, we are proposing to apply a permanent 5-percent cap on any ESRD facility's wage index decrease from its wage index in the prior year, regardless of the circumstances causing the decline.
- *Wage index floor:* We are proposing to raise the wage index floor, for areas with wage index values below the floor, from 0.5000 to 0.6000.
- *Outlier policy refinement:* The ESRD PPS has an outlier policy that targets 1.0 percent of total Medicare ESRD PPS expenditures in outlier payments for ESRD beneficiaries who require a high level of renal dialysis services. We are proposing to modify the methodology for calculating the fixed-dollar loss (FDL) amounts for adult patients.
- *Annual update to the outlier policy:* We are proposing to update the outlier policy based on the most current data and our proposed refinement to the outlier policy. Accordingly, we propose to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2023 using the latest available CY 2021 claims data. We propose to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2021 claims data, and we propose to use the latest available claims data from CY 2019, CY 2020, and CY 2021 to calculate the FDL amount for adults, in accordance with the proposed methodology discussed in section II.B.1.c.(4) of this proposed rule. For pediatric beneficiaries, the proposed FDL amount would decrease from $26.02 to $21.51, and the proposed MAP amount would decrease from $27.15 to $25.62, as compared to CY 2022 values. For adult beneficiaries, the proposed FDL amount would decrease from $75.39 to $40.75, and the proposed MAP amount would decrease from $42.75 to $36.85. The 1.0 percent target for outlier payments was not achieved in CY 2021. Outlier payments represented approximately 0.4 percent

of total payments rather than 1.0 percent.

- *Definition of oral-only drugs:* We are proposing that, beginning January 1, 2025, we would include the word functional in the definition of oral-only drug at § 413.234(a). Specifically, under the proposed definition, an oral-only drug would be a drug or biological product with no injectable *functional* equivalent or other form of administration other than an oral form.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2023:* The proposed CY 2023 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $9.73. This proposed offset amount reflects the application of the productivity-adjusted market basket increase of 2.4 percent ($9.50 × 1.024 = $9.73).
- *TPNIES applications received for CY 2023:* This proposed rule presents a summary of the three CY 2023 TPNIES applications that we received by the February 1, 2022 deadline and our preliminary analysis of the applicants' claims related to substantial clinical improvement and other eligibility criteria for the TPNIES.

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

We are proposing to update the AKI payment rate for CY 2023. The proposed CY 2023 payment rate is $264.09, which is the same as the base rate proposed under the ESRD PPS for CY 2023.

3. ESRD QIP

We are proposing to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, the Long-Term Catheter Rate clinical measure, the Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and the Kt/V Dialysis Adequacy Comprehensive clinical measure for PY 2023 under our previously finalized measure suppression policy because we have determined that circumstances caused by the public health emergency (PHE) due to COVID–19 have significantly affected the measures and resulting performance scores. We are also proposing to use CY 2019 data to calculate performance standards for the PY 2023 ESRD QIP. We are also updating the technical specifications of the SHR clinical measure and SRR clinical measure so that the measure results are expressed as rates instead of ratios beginning with the PY 2024 ESRD QIP. Beginning with the PY 2025 ESRD QIP, we are proposing to add the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure to the ESRD QIP measure set. We are also proposing to convert the Standardized Transfusion Ratio (STrR) reporting measure to a clinical measure beginning with PY 2025, and are further proposing to express the measure as a rate to align with the technical updates to express the SHR and SRR clinical measure results as rates. In addition, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure, beginning with PY 2025. Furthermore, we are proposing to create a new Reporting Measure domain and to re-weight current measure domains beginning with PY 2025.

This proposed rule also includes requests for information on several important topics, including potential quality measures for home dialysis, the expansion of our quality reporting programs to allow us to provide more actionable and comprehensive information on health care disparities across multiple variables and new care settings, and on the possible future inclusion of two potential social drivers of health screening measures.

4. ETC Model

We are proposing to update the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY5) of the ETC Model, which begins January 1, 2023. We are also proposing to clarify the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers. In addition, we discuss our intent to disseminate participant-level model performance information to the public.

C. Summary of Costs and Benefits

In section VII.D.5 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 table in section VII.D.5.a of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2023 compared to estimated payments in CY 2022. The overall impact of the CY 2023 changes is projected to be a 3.1 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.7 percent increase in payments compared with freestanding facilities with an estimated 3.1 percent increase. We estimate that the aggregate ESRD PPS expenditures would increase by approximately $320 million in CY 2023 compared to CY 2022. This reflects a $250 million increase from the proposed payment rate update, a $70 million increase due to the proposed updates to the outlier threshold amounts, and approximately $2.5 million in estimated TPNIES amounts. Because of the projected 3.1 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

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

The impact table in section VII.D.5.b of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2023 compared to estimated payments in CY 2022. The overall impact of the CY 2023 changes is projected to be a 2.4 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.1 percent increase in payments compared with freestanding ESRD facilities with an estimated 2.4 percent increase. The overall impact reflects the effects of the proposed update to the labor-related share, proposed CY 2023 wage index, proposed permanent cap on wage index decreases, and the proposed payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the proposed CY 2023 ESRD PPS base rate, would increase by $2 million in CY 2023 compared to CY 2022.

3. Impacts of the Proposed ESRD QIP

Our proposals to suppress measures for the PY 2023 ESRD QIP necessitate a modification to our previously estimated overall economic impact of the PY 2023 ESRD QIP (85 FR 71400). In the CY 2021 ESRD PPS final rule, we estimated that the overall economic impact of the PY 2023 ESRD QIP would be approximately $224 million as a result of the policies we had finalized at that time. The $224 million figure for PY 2023 included costs associated with the collection of information requirements, which we estimated would be approximately $208 million, and $16 million in estimated payment reductions across all facilities. However, as a result of the proposals impacting the PY 2023 ESRD QIP that we are making in this proposed rule, we are modifying our previous estimate. We now estimate that the overall economic

impact of the PY 2023 ESRD QIP would be approximately $218 million. The $218 million figure for PY 2023 includes costs associated with the collection of information requirements and recalculated estimated payment reductions based on the six measures we are proposing to suppress for PY 2023. Although we are updating the way we express the SHR clinical measure and the SRR clinical measure results beginning with PY 2024, these technical updates would not impact our previously estimated economic impact for the PY 2024 ESRD QIP. We estimate that the overall economic impact of the PY 2025 ESRD QIP would be approximately $252 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The $252 million figure for PY 2025 includes costs associated with the collection of information requirements, which we estimate would be approximately $215 million, and $37 million in estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2026 ESRD QIP would be approximately $252 million as a result of the policies we have previously finalized. The $252 million figure for PY 2026 includes costs associated with the collection of information requirements, which we estimate would be approximately $215 million, and $37 million in estimated payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The impact estimate in section VII.D.5.d of this proposed rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the proposed changes. We estimate that the ETC Model would result in $28 million in net savings over the 6.5 year duration of the ETC Model. We also estimate that the changes proposed in this proposed rule would produce no change in net savings for the ETC Model.

II. CY 2023 ESRD PPS

A. Background

1. Statutory Background

On January 1, 2011, CMS 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 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 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. 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 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 definition 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, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 22, or age 22 to 26) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 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 payment 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).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment

for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a 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.

We published a final rule, which appeared in the November 8, 2021 issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2022 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2022. We also updated the average per treatment offset amount for the TPNIES for CY 2022. In addition, we announced our approval of one application for the TPNIES for CY 2022 payment. For further detailed information regarding these updates, see 86 FR 61874.

B. Provisions of the Proposed Rule

1. Proposed CY 2023 ESRD PPS Update

a. Proposed CY 2023 ESRD Bundled (ESRDB) Market Basket Rebasing and Revision; Market Basket Increase Factor; Productivity Adjustment; and Labor-Related Share

(1) Proposed Rebasing and Revising of the ESRDB Market Basket

(a) Background

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. Section 1881(b)(14)(F)(i) of the Act 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 included in 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 using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. Effective for CY 2023, we are proposing to rebase and revise the ESRDB market basket to a base year of CY 2020.

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

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

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

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

We last rebased the ESRDB market basket cost weights effective for CY 2019 (83 FR 56951 through 56964), with 2016 data used as the base period for the construction of the market basket cost weights. We are proposing to use 2020 as the base year for the proposed rebased ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the proposed market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2020 (that is, the average index level for CY 2020 is equal to 100). The major source data for the proposed ESRDB market basket is the 2020 Medicare cost reports (MCRs) (Form CMS–265–11, OMB NO. 0938–0236), supplemented with 2012 data from the United States (U.S.) Census Bureau's Services Annual Survey (SAS) inflated to 2020 levels. The 2012 SAS data is the most recent year of detailed expense data published by the Census Bureau for North American International Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We also are proposing to use May 2020

Occupational Employment Statistics data from the U.S. Department of Labor's Bureau of Labor Statistics (BLS) to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends. We provide more detail on our proposed methodology in section II.B.1.a.(1)(b) of this proposed rule.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in this exercise, we are proposing to move the base year cost structure from 2016 to 2020) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and/or price proxies used in the input price index. For CY 2023, we are proposing to rebase the ESRDB market basket to reflect the 2020 cost structure of ESRD facilities and to revise the index, that is, make changes to cost categories or price proxies used in the index.

We are proposing CY 2020 as the new base year because 2020 is the most recent year for which relatively complete MCR data are available. We analyzed the cost weights for the years 2017 through 2020 and found that the expenses reported in the ESRD facility MCRs for 2020 were consistent with those in the prior years. Additionally, given the nature of renal dialysis services, any impacts on utilization due to the COVID–19 PHE were minimal as dialysis is not an optional treatment and must continue even during the PHE. In developing the proposed market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11, OMB NO. 0938–0236) for 2020 for each freestanding ESRD facility that reported expenses and payments. The 2020 MCRs are for those ESRD facilities whose cost reporting period began on or after October 1, 2019, and before October 1, 2020. Of the 2020 MCRs, approximately 91 percent of freestanding ESRD facilities had a begin date on January 1, 2020, approximately 5 percent had a begin date prior to January 1, 2020, and approximately 4 percent had a begin date after January 1, 2020. Using this methodology allowed our sample to include ESRD facilities with varying cost report years including, but not limited to, the federal fiscal year (FY) or CY.

We are proposing to maintain our policy of using data from freestanding ESRD facilities (which account for over 90 percent of total ESRD facilities in CY 2020) because freestanding ESRD facility data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for hospital-based ESRD facilities reflect the allocation of overhead from the entire institution.

We developed cost category weights for the proposed 2020-based ESRDB market basket in two stages. First, we derived base year cost weights for ten major categories (Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Laboratory Services, Housekeeping, Operations & Maintenance, Administrative & General, Capital-Related Building and Fixtures, and Capital-Related Moveable Equipment) from the ESRD MCRs. Second, we are proposing to divide the Administrative & General cost category into further detail using 2012 SAS data for the industry Kidney Dialysis Centers NAICS 621492 inflated to 2020 levels. We apply the estimated 2020 distributions from the SAS data to the 2020 Administrative & General cost weight to yield the more detailed 2020 cost weights in the proposed market basket. This is the same methodology we used in the CY 2019 ESRD PPS rulemaking to break the Administrative & General costs into more detail for the 2016-based ESRDB market basket (83 FR 56951 through 56964).

We are proposing to include a total of 21 detailed cost categories for the proposed 2020-based ESRDB market basket, whereas the 2016-based ESRDB market basket had 20 detailed cost categories. A detailed discussion of the proposals is provided in section II.B.1.a.(1)(b) of this proposed rule.

(b) Cost Category Weights

Using Worksheets A and B from the 2020 MCRs, we first computed cost shares for ten major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Laboratory Services, Housekeeping, Operations & Maintenance, Administrative and General, Capital-Related Building and Fixtures, and Capital-Related Moveable Equipment. Edits were applied to include only cost reports that had total costs greater than zero. Total costs as reported on the MCR include those costs reimbursable under the ESRD PPS. For example, we excluded expenses related to vaccine costs from total expenditures since these are not paid for under the ESRD PPS.

In order to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The proposed data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 6,625 independent ESRD facilities' cost reports from an available pool of 7,413 cost reports.

Table 1 presents the proposed 2020-based ESRDB and 2016-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 1: Proposed 2020-based ESRDB Market Basket Major Cost Weights Derived from the Medicare Cost Report Data

Cost Category	Proposed 2020-based ESRDB Market Basket (%)	2016-based ESRDB Market Basket (%)
Wages and Salaries	34.5	32.6
Employee Benefits	7.7	7.0
Pharmaceuticals	10.1	12.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Administrative & General	17.5	18.5
Capital-related Building and Fixtures	9.4	9.2
Capital-related Moveable Equipment	4.4	3.8

Note: Totals may not sum to 100.0 percent due to rounding.
* For the 2016-based ESRDB market basket, this category was referred to as the Housekeeping and Operations cost category. For the proposed 2020-based ESRDB market basket, the Housekeeping and Operations cost category is split into two detailed cost categories: Housekeeping and Operations & Maintenance.

We are proposing to disaggregate the Administrative & General major cost category developed from the MCR into more detail to more accurately reflect ESRD facility costs. Those categories include: Benefits, Professional Fees, Telephone, Utilities, and All Other Goods and Services. We describe below how the initially computed categories and weights from the cost reports were modified to yield the proposed 2020 ESRDB market basket expenditure categories and weights presented in this proposed rule.

Wages and Salaries

The proposed Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 2020 was derived from Worksheet B, column 5, lines 8 through 17 of the MCR. Non-direct patient care wages and salaries includes all other wages and salaries costs for non-health workers and physicians, which we are proposing to derive using the following steps:

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

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

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

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

Using this methodology, we derive a proposed Wages and Salaries cost weight of 34.5 percent, reflecting an estimated direct patient care wages and salaries cost weight of 25.7 percent and non-direct patient care wages and salaries cost weight of 8.9 percent, as seen in Table 2.

The final adjustment made to this category is to include Contract Labor costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid double counting of these expenses we are proposing to move the estimated cost weight for the contract labor costs from the Administrative and General category (where we believe the majority of the contract labor costs would be reported) to the Wages and Salaries category. We are proposing to use data from the SAS (2012 data inflated to 2020), which reported 2.4 percent of total expenses were spent on contract labor costs. We allocated 80 percent of that contract labor cost weight to the Wages and Salaries category. At the same time, we subtracted that same amount from the Administrative and General category, where the majority of contract labor expenses would likely be reported on the MCR. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2020 MCR data. This is the same method that was used to allocate contract labor costs to the Wages and Salaries cost category

for the 2016-based ESRDB market basket.

The resulting proposed cost weight for Wages and Salaries increases to 36.5 percent when contract labor wages are added. The calculation of the proposed Wages and Salaries cost weight for the 2020-based ESRDB market basket is shown in Table 2 along with the similar calculation for the 2016-based ESRDB market basket.

TABLE 2: Proposed 2020 and 2016 ESRD Wages and Salaries Cost Weight Determination

Components	Proposed 2020 Cost Weight	2016 Cost Weight	Source
Wages and Salaries Direct Patient Care	25.2%	25.1%	MCR
Wages and Salaries Non-direct Patient Care	8.9%	7.5%	MCR
Contract Labor (Wages)	1.9%	1.9%	80% of SAS Contract Labor weight
Total Wages and Salaries	**36.5%**	**34.5%**	

Employee Benefits

The proposed Employee Benefits cost weight was derived from the MCR data for direct patient care and supplemented with data from the SAS (2012 data inflated to 2020) to account for non-direct patient care Employee Benefits. The MCR data only reflects Employee Benefit costs associated with health and wellness; that is, it does not reflect retirement benefits.

In order to reflect the benefits related to non-direct patient care for employee health and wellness, we estimated the impact on the benefit weight using SAS. Unlike the MCR, the SAS collects detailed expenses for employee benefits including expenses related to the retirement and pension benefits. Incorporating the SAS data produced an Employee Benefits (both direct patient care and non-direct patient care) weight that was 1.3 percentage points higher (9.0 vs. 7.7) than the Employee Benefits weight for direct patient care calculated directly from the MCR. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.3 percentage points for Non-Direct Patient Care Employee Benefits from the Administrative and General cost category.

The final adjustment made to this category is to include contract labor benefit costs. Once again, these costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCR data. Identical to our methodology previously for allocating Contract Labor Costs to Wages and Benefits, we applied 20 percent of total Contract Labor Costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The 20 percent figure was determined by taking benefits as a percentage of total compensation (excluding contract labor) from the 2020 MCR data. The resulting cost weight for Employee Benefits increases to 9.5 percent when contract labor benefits are added. This is the same method that was used to allocate contract labor costs to the Benefits cost category for the 2016-based ESRDB market basket.

Table 3 compares the 2016-based Benefits cost share derivation as detailed in the CY 2019 ESRD PPS final rule (83 FR 56954) to the proposed 2020-based Benefits cost share derivation.

TABLE 3: Proposed 2020 and 2016 ESRD Employee Benefits Cost Weight Determination

Components	Proposed 2020 Cost Weight	2016 Cost Weight	Source
Employee Benefits Direct Patient Care	7.7%	7.0%	MCR
Employee Benefits Non-direct Patient Care	1.3%	1.6%	SAS
Contract Labor (Benefits)	0.5%	0.5%	20% of SAS Contract Labor weight
Total Employee Benefits	**9.5%**	**9.1%**	

Pharmaceuticals

The proposed 2020-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and all other ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We calculated a Pharmaceuticals cost weight from the following cost centers on Worksheet B, the sum of lines 8 through 17, for the following columns: column 11, ''Drugs Included in Composite Rate,'' column 12, ''Erythropoiesis stimulating agents (ESAs)''; and column 13, ''ESRD-Related and AKI -Related Drugs.'' We did not include the drug expenses for Non-ESRD Related Drugs, Supplies, and Labs as reported on line 5, column 10 or the AKI Non-Renal Related Drugs, Supplies, & Lab as reported on line 5.01 column 10 as these expenses are not included in the ESRD PPS bundled payment amount. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, COVID–19, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these vaccines are not paid for under the ESRD PPS, we did not include expenses reported on worksheet B, column 9 line 7 in the proposed 2020-based ESRDB market basket.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with the applicable pharmaceutical cost centers referenced previously. This resulted in a proposed ESRDB market basket weight for Pharmaceuticals of 10.1 percent. ESA expenditures accounted for 6.0 percentage points of the proposed Pharmaceuticals cost weight, and All Other Drugs accounted for the remaining 4.1 percentage points.

The Pharmaceuticals cost weight decreased 2.3 percentage points from the 2016-based ESRDB market basket to the proposed 2020-based ESRDB market basket (12.4 percent to 10.1 percent). Most ESRD facilities experienced a decrease in their Pharmaceuticals cost weight since 2016.

Supplies

We calculated the proposed Supplies cost weight using the costs reported in the Supplies cost center (Worksheet B, line 5 and the sum of lines 8 through 17, column 7) of the MCR. To avoid double-counting, the Supplies costs were reduced to exclude the estimated share of Non-Direct patient care Wages and Salaries associated with this cost center. The resulting proposed 2020-based ESRDB market basket weight for Supplies is 11.0 percent, approximately 0.6 percentage point higher than the weight for the 2016-based ESRDB market basket.

Laboratory Services

We calculated the proposed Laboratory Services cost weight using the costs reported in the Laboratory cost center (Worksheet B, line 5 and the sum of line 8 through 17, column 8) of the MCR. To avoid double-counting, the Laboratory Services costs were reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The proposed 2020-based ESRDB market basket weight for Laboratory Services is estimated at 1.3 percent, which is a 0.9 percentage point decrease from the 2016-based ESRDB market basket.

Housekeeping

We calculated the proposed Housekeeping cost weight using the costs reported on Worksheet A, line 4, column 8, of the MCR. To avoid double-counting, the weight for the Housekeeping category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. These costs were divided by total costs to derive a proposed 2020-based ESRDB market basket weight for Housekeeping of 0.5 percent. For the 2016-based ESRDB market basket the cost category weight for both Housekeeping and Operations costs were combined into a single cost weight. The Housekeeping cost weight in the 2016-based ESRDB market basket would have been 0.5 percent if it had been broken out separately.

Operations & Maintenance

We are proposing a new Operations & Maintenance cost category that includes the direct expenses incurred in the operation and maintenance of the plant and equipment such as heat, light, water (excluding water treatment for dialysis purposes), air conditioning, and air treatment; the maintenance and repair of building, parking facilities, and equipment; painting; elevator maintenance; performance of minor renovation of buildings and equipment; and protecting employees, visitors, and facility property. As previously discussed, these costs had formerly been combined with the Housekeeping expenses in a single cost category for Housekeeping and Operations. The proposed 2020-based ESRDB market basket Operations & Maintenance cost category reflects the expenses for Operations & Maintenance, which also includes the costs for Water and Sewerage that was a stand alone cost category in the 2016-based ESRDB market basket. We calculated the Operations & Maintenance cost weight using the costs reported on Worksheet A, line 3, column 8, of the MCR. To avoid double-counting, the weight for the Operations & Maintenance category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The resulting proposed 2020-based ESRDB market basket weight for Operations & Maintenance is 3.7 percent.

Capital

We developed a proposed market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. The MCR captures Capital-related Costs including: (1) Capital-Related- Building and Fixtures (2) Capital-Related Costs—Moveable Equipment and (3) Housekeeping, and Operations & Maintenance costs in Worksheet B, column 2. Since we developed separate expenditure categories for Housekeeping, and Operations & Maintenance, as detailed previously, we excluded these costs from the Capital cost weights. To calculate the Capital-related Buildings and Fixtures cost weight we sum expenses reported in Worksheet B lines 8 through 17, column 2 less Housekeeping, Operations & Maintenance (as derived from expenses reported on Worksheet A, as described previously), and less Capital-related Moveable equipment costs (calculated as Worksheet A, column 8, line 2 divided by the sum of Worksheet A, column 8, lines 1 and 2). The Capital-related moveable equipment cost weight is equal to Capital-related Renal Dialysis Equipment costs (Worksheet B, the sum of lines 8 through 17, column 4 plus Capital-Related Moveable Equipment (as described in the prior sentence)). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Fixtures could move differently than those associated with Machinery, we continue to believe that two capital-related cost categories are appropriate. The resulting proposed 2020-based ESRDB market basket weights for Capital-related

Buildings and Fixtures and Capital-related Moveable Equipment are 9.4 and 4.4 percent, respectively.

Administrative & General

We computed the proportion of total Administrative & General expenditures using the Administrative and General cost center data from Worksheet B, the sum of lines 8 through 17, (column 9) of the MCRs. Additionally, we removed contract labor from this cost category and apportioned these costs to the Wages and Salaries and Employee Benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude Wages and Salaries and Benefits associated with the Administrative and General cost center for Non-direct Patient Care as estimated from the SAS data. The resulting Administrative and General cost weight is 13.7 percent.

We are proposing to further disaggregate the Administrative and General cost weight to derive detailed cost weights for Electricity, Natural Gas, Telephone, Professional Fees, and All Other Goods and Services. These detailed cost weights were derived by inflating the detailed 2012 SAS data forward to 2020 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 SAS data. We repeated this practice for each year to 2020. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2020. These resulting 2020 cost shares were applied to the Administrative and General cost weight derived from the MCR (net of contract labor and additional benefits) to obtain the detailed cost weights for the proposed 2020-based ESRDB market basket. This method is similar to the method used for the 2016-based ESRDB market basket.

Table 4 lists all of the cost categories and cost weights in the proposed 2020-based ESRDB market basket compared to the 2016-based ESRDB market basket.

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TABLE 4: Comparison of the Proposed 2020-based and the 2016-based ESRDB Market Basket Cost Categories and Weights

Proposed 2020 Cost Category	Proposed 2020 Cost Weights (percent)	2016 Cost Weights (percent)
Total	100.0	**100.0**
Compensation	**45.9**	**43.6**
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Utilities	**1.4**	**2.0**
Electricity	1.2	1.1
Natural Gas	0.1	0.1
Water and Sewerage	n/a	0.8
Medical Supplies & Laboratory Services	**22.4**	**24.9**
Pharmaceuticals	10.1	12.4
ESAs	6.0	10.0
Other Drugs (except ESAs)	4.1	2.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
All Other Goods and Services	**16.6**	**16.4**
Telephone & Internet Services	0.5	0.5
Housekeeping	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees	0.8	0.7
All Other Goods and Services	11.1	11.3
Capital Costs	**13.8**	**13.0**
Capital Related-Building and Fixtures	9.4	9.2
Capital Related-Machinery	4.4	3.8

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

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(c) Proposed Price Proxies for the 2020-Based ESRDB Market Basket

After developing the cost weights for the proposed 2020-based ESRDB market basket, we are proposing to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based the proposed price proxies on BLS data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs are available.

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

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

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

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

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

Table 7 lists all proposed price proxies for the proposed 2020-based ESRDB market basket. We note that we are proposing to use the same proxies as those used in the 2016-based ESRDB market basket, except for the price proxy for the Other Drugs (except ESAs) cost category. Below is a detailed explanation of the proposed price proxies used for each cost category.

Wages and Salaries

We are proposing to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the proposed 2020-based ESRDB market basket, and to continue using four occupational categories and associated ECIs based on full-time equivalents (FTE) data from ESRD MCRs and ECIs from BLS. We calculated occupation weights for the blended Wages and Salaries price proxy using 2020 FTE data from the MCR data multiplied by the associated 2020 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics. This is similar to the methodology used in the 2016-based ESRDB market basket to derive these occupational wages and salaries categories.

Health Related Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (''Hospitals'' and ''Health Care and Social Assistance''), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.4 percent of total Wages and Salaries in 2020. The ESRD MCR FTE categories used to define the Wages and Salaries—Health Related subcategory include ''Physicians,'' ''Registered Nurses,'' ''Licensed Practical Nurses,'' ''Nurses' Aides,'' ''Technicians,'' and ''Dieticians''.

Management Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities.

The Wages and Salaries—Management subcategory weight within the Wages and Salaries cost category is 9.0 percent in 2020. The ESRD MCR FTE category used to define the Wages and Salaries—Management subcategory is ''Management.''

Administrative Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities.

The Wages and Salaries—Administrative subcategory weight within the Wages and Salaries cost category is 5.3 percent in 2020. The ESRD MCR FTE category used to define the Wages and Salaries—Administrative subcategory is ''Administrative.''

Services Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-

administrative service support personnel at ESRD facilities.

The Services subcategory weight within the Wages and Salaries cost category is 6.3 percent in 2020. The ESRD MCR FTE categories used to define the Wages and Salaries—Services subcategory are ''Social Workers'' and ''Other.''

Table 5 lists the four ECI series and the corresponding weights used to construct the proposed ECI blend for Wages and Salaries compared to the 2016-based weights for the subcategories. We believe this proposed ECI blend is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

TABLE 5: Proposed ECI Blend for Wages and Salaries in the Proposed 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	Proposed 2020 Weight	2016 Weight
Health Related	ECI for Wages and Salaries for All Civilian Workers in Hospitals	79.4%	79.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial	9.0%	6.7%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support	5.3%	7.7%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations	6.3%	5.7%

Employee Benefits

We are proposing to continue using an ECI blend for Employee Benefits in the proposed 2020-based ESRDB market basket where the components match those of the proposed Wage and Salaries ECI blend. The proposed occupation weights for the blended Benefits price proxy (Table 6) are the same as those proposed for the wages and salaries price proxy blend as shown in Table 5. BLS does not publish ECI for Benefits price proxies for each Wage and Salary ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index.

Health Related Benefits

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

Management Benefits

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU20100001100000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Administrative Benefits

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

Services Benefits

We are proposing to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. We believe this ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section. We believe the proposed benefits ECI blend continues to be the most appropriate price proxy to measure the growth of benefits prices faced by ESRD facilities. Table 6 lists the four ECI series and the corresponding weights used to construct the proposed benefits ECI blend.

TABLE 6: Proposed ECI Blend for Benefits in the Proposed 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	Proposed 2020 Weight	2016 Weight
Health Related	ECI for Benefits for All Civilian Workers in Hospitals.	79.4%	79.9%
Management	ECI for Benefits for Private Industry Workers in Management, Business, and Financial.	9.0%	6.7%
Administrative	ECI for Benefits for Private Industry Workers in Office and Administrative Support.	5.3%	7.7%
Services	ECI for Benefits for Private Industry Workers in Service Occupations.	6.3%	5.7%

Electricity

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

Natural Gas

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

Pharmaceuticals

ESAs: We are proposing to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI–BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. The PPI–BPHU measures the price change of prescription biologics, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI–BPHU and the average sales price (ASP) for ESAs and found the cumulative growth to be consistent over the past 4 years. We would continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

Other Drugs (except ESA): For all other drugs included in the ESRD PPS bundled payment other than ESAs, we are proposing to use a blend of 50 percent of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI–VNHP) (BLS series code #WPU063807), and 50 percent of the PPI Commodity for Pharmaceuticals for human use, prescription (which we will abbreviate as PPI-Pharmaceuticals) (BLS series code #WPUSI07003). We continue to believe that the PPI–VNHP is an appropriate price proxy for the iron supplements commonly used in the treatment of ESRD, and an analysis of claims data indicate that iron supplement costs account for about half of the All Other ESRD-related Drugs costs. For the remaining drugs represented in the non-ESA drug category (such as calcimimetics and Vitamin D analogs) we believe a different price proxy would be more appropriate and we are proposing to use the PPI Commodity for Pharmaceuticals for human use, prescription, which captures the inflationary price pressures for all types of prescription drugs rather than a single therapeutic category of drugs. Though this PPI measure includes a wide variety of prescription drugs, we believe it is technically appropriate to use a broad indicator of prescription drug price trends for three key reasons: (1) the more detailed PPI measure where we believe these types of non-ESA drugs would be captured would more likely reflect price trends not faced by ESRD facilities, such as cancer drugs, (2) there have been notable changes to the types and mix of drugs paid for under the ESRD PPS bundled payment since 2016, such as the inclusion of formerly oral-only calcimimetics and the addition of AKI-related drugs, and (3) the potential for future changes to the types and mix of drugs that may be paid for under the ESRD PPS bundled payment, such as when other drugs that are currently oral-only drugs are included in the ESRD PPS beginning for CY 2025. For these reasons, we believe that a broader drug index representing a larger mix of prescription drugs is a technical improvement to the proposed price proxy for this cost category. We will continue to monitor the relative share of expenses for iron supplements and other types of drugs for this cost category to determine if the proposed 50/50 PPI blend warrants an adjustment, and if so, we would propose such an adjustment in future rulemaking.

Supplies

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

Laboratory Services

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

Telephone Service

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

Housekeeping

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

Operations & Maintenance

For the Operations & Maintenance cost category, we are proposing to use the ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair (BLS series code #CIU10100004300001) to measure the price growth of this cost category.

This price proxy accounts for the compensation expenses related to maintenance and repair workers. We believe the majority of expenses for maintenance and repair to be labor-related costs and therefore, believe that this ECI is the most technically appropriate price proxy for this cost category.

Professional Fees

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

All Other Goods and Services

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

Capital-Related Building and Fixtures

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

Capital-Related Moveable Equipment

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

Table 7 shows all the proposed price proxies and cost weights for the proposed 2020-based ESRDB Market Basket.

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TABLE 7: Proposed Price Proxies and associated Cost Weights for the 2020-based ESRDB Market Basket

Cost Category	Price Proxy	Proposed 2020 Cost Weight
Total ESRDB Market Basket		100.0%
Compensation		**45.9%**
Wages and Salaries		36.5%
Health-related	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	28.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	3.3%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	1.9%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	2.3%
Employee Benefits		9.5%
Health-related	ECI for Total Benefits for All Civilian workers in Hospitals.	7.5%
Management	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.9%
Administrative	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.5%
Services	ECI for Total Benefits for Private Industry workers in Service Occupations.	0.6%
Utilities		**1.4%**
Electricity	PPI Commodity for Commercial Electric Power.	1.2%
Natural Gas	PPI Commodity for Commercial Natural Gas.	0.1%
Medical Materials and Supplies		**22.4%**
Pharmaceuticals		10.1%
ESAs	PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use.	6.0%
Other Drugs	50/50 blend of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations, and the PPI Commodity for Pharmaceuticals for human use, prescription	4.1%
Supplies	PPI Commodity for Surgical and Medical Instruments.	11.0%
Laboratory Services	PPI Industry for Medical Laboratories.	1.3%
All Other Goods and Services		**16.6%**
Telephone Service	CPI-U for Telephone Services.	0.5%
Housekeeping	PPI Commodity for Cleaning and Building Maintenance Services.	0.5%
Operations & Maintenance	ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair	3.7%
Professional Fees	ECI for Total Compensation for Private Industry Workers in Professional and Related.	0.8%
All Other Goods and Services	PPI for Final demand - Finished Goods less Foods and Energy.	11.1%
Capital Costs		**13.8%**
Capital Related Building and Fixtures	PPI Industry for Lessors of Nonresidential Buildings.	9.4%
Capital Related Moveable Equipment	PPI Commodity for Electrical Machinery and Equipment.	4.4%

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

(d) Proposed Rebasing Results

A comparison of the yearly differences of increase factors from CY 2019 to CY 2023 for the 2016-based ESRDB market basket and the proposed 2020-based ESRDB market basket is shown in Table 8. The CY 2023 ESRDB market basket increase factor would be 0.2 percentage point lower if we continued to use the 2016-based ESRDB market basket. For the years prior to CY 2023 the annual market basket increase factors were the same, except for CY 2021 where the proposed 2020-based market basket was 0.1 percentage point lower.

TABLE 8: Historical and Projected Market Basket Increase Factors under the Proposed 2020-based ESRDB Market Basket and 2016-based ESRDB Market Basket

Calendar Year (CY)	Proposed 2020-based ESRDB Market Basket	2016-based ESRDB Market Basket	Proposed 2020-based ESRDB Market Basket less 2016-based ESRDB Market Basket
Historical Data:			
CY 2019	2.3	2.3	0.0
CY 2020	1.9	1.9	0.0
CY 2021	3.0	3.1	-0.1
Forecast:			
CY 2022	4.5	4.5	0.0
CY 2023	2.8	2.6	0.2

Source: IHS Global Inc. 1st quarter 2022 forecast with historical data through 4th quarter 2021

(2) Proposed Labor-Related Share for ESRD PPS

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market.

We are proposing to use the proposed 2020-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Therefore, effective for CY 2023, we are proposing a labor-related share of 55.2 percent, compared to the current 52.3 percent that was based on the 2016-based ESRDB market basket, as shown in Table 9. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping, Operations & Maintenance, 87 percent of the weight for Professional Fees (details discussed later in this subsection), and 46 percent of the weight for Capital-related Building and Fixtures expenses (details discussed later in this subsection). We used the same methodology for the 2016-based ESRDB market basket.

TABLE 9: Labor-Related Share of Current and Proposed ESRD Bundled Market Baskets

Cost Category	Proposed 2020-based ESRDB Market Basket Weights	2016-based ESRDB Market Basket Weights
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees (Labor-Related)	0.7	0.6
Capital Labor-Related	4.3	4.2
Total Labor-Related Share	55.2	52.3

*The 2016-based ESRDB labor-related share had a combined category weight for Housekeeping and Operations

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The proposed labor-related share for Professional Fees reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market (87 percent). We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional

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

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

(3) Proposed CY 2023 ESRD Market Basket Increase Factor, Adjusted for Productivity

Under section 1881(b)(14)(F)(i) of the Act, beginning in CY 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We are proposing to use the 2020-based ESRDB market basket as described in section II.B.1 of this proposed rule to compute the CY 2023 ESRDB market basket increase factor and labor-related share based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket increase factor based on IHS Global Inc.'s (IGI) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets.

(a) Proposed CY 2023 Market Basket Increase Factor

Using this methodology and the IGI forecast available in the first quarter of 2022 of the proposed 2020-based ESRDB market basket (with historical data through the fourth quarter of 2021), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2023 ESRDB market basket increase factor is 2.8 percent.

(b) Proposed Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70235).

BLS publishes the official measures of productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.[1] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We refer readers to *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.* In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, CMS would be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Using this methodology and IGI's first quarter 2022 forecast, the proposed productivity adjustment for CY 2023 (the 10-year moving average of TFP for the period ending CY 2023) is projected to be 0.4 percentage point.

(c) Proposed CY 2023 Market Basket Increase Factor Adjusted for Productivity

As a result of these provisions, the proposed CY 2023 ESRD market basket increase factor reduced by the productivity adjustment is 2.4 percent. This proposed market basket increase factor is calculated by starting with the proposed 2020-based ESRDB market basket percentage increase factor of 2.8 percent for CY 2023, and reducing it by the proposed productivity adjustment (the 10-year moving average of TFP for the period ending CY 2023) of 0.4 percentage point. As is our general practice, we are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket increase factor or productivity adjustment), we would use such data to determine the market basket increase factor and productivity adjustment in the CY 2023 ESRD PPS final rule.

b. Proposed CY 2023 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 OMB's CBSA-based

[1] Total Factor Productivity in Major Industries—2020. Available at: *https://www.bls.gov/news.release/prod5.nr0.htm.*

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 2023, we are proposing to 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 prefloor hospital data that are unadjusted for occupational mix. For CY 2023, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019 (FY 2019 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 the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state 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).

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 was based on the 2016-based ESRDB market basket. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the 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 finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the 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. For CY 2023, as discussed in section II.B.1.a (2) of this proposed rule, the proposed labor-related share to which the wage index would be applied is 55.2 percent, based on the proposed 2020-based ESRDB market basket.

For CY 2023, we are proposing to update the ESRD PPS wage index to use the most recent hospital wage data. The proposed CY 2023 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.* Addendum A provides a crosswalk between the CY 2022 wage index and the proposed CY 2023 wage index. Addendum B provides an ESRD facility level impact analysis. 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.*

(2) Proposed Permanent Cap on Wage Index Decreases

As discussed in section II.B.1.b(1) of this proposed rule and in previous ESRD PPS rules, under the authority of section 1881(b)(14)(D)(iv)(II) of the Act, we have proposed and finalized temporary, budget-neutral transition policies in the past to help mitigate negative impacts on ESRD facilities following the adoption of certain ESRD PPS wage index changes. In the CY 2015 ESRD PPS final rule (79 FR 66142), we implemented revised OMB area delineations using a 2-year transition, with a 50/50 blended wage index for all ESRD facilities in CY 2015 [2] and 100 percent of the wage index based on the new OMB delineations in CY 2016. In the CY 2021 ESRD PPS proposed rule (85 FR 42160 through 42161), we proposed a transition policy to help mitigate any negative impacts that ESRD facilities may experience due to our proposal to adopt the 2018 OMB delineations under the ESRD PPS. We noted that because the overall amount of ESRD PPS payments would increase slightly due to the 2018 OMB delineations, the effect of the wage index budget neutrality factor would be to 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 2018 OMB delineations. Thus, we explained that we believed 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. We proposed to apply a 5-percent cap on any decrease in an ESRD facility's wage index from its final wage index from the prior calendar year, that is, CY 2020. We explained that we believed the 5-percent cap would provide greater transparency and would be administratively less complex than the prior methodology of applying a 50/50 blended wage index (85 FR 71478). We proposed that no cap would be applied to the reduction in the wage index for the second year, that is, CY 2022 (85 FR 42161).

Several commenters to the CY 2021 ESRD PPS proposed rule supported the wage index transition policy that we proposed for CY 2021; however, as discussed in the CY 2021 ESRD PPS final rule (86 FR 71434 through 71436), some commenters expressed concerns about the large negative effects of the new labor market area delineations on certain areas. A patient organization suggested that the 5 percent cap may not provide an adequate transition for labor market areas that would experience a decrease in their wage index of greater than 10 percent. Similarly, a national non-profit dialysis organization recommended that CMS provide an extended transition period, beyond the proposed 5 percent limit for 2021, for at least 3 years. Some commenters, including MedPAC, suggested

[2] 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 newer OMB delineations. 79 FR 66142.

alternatives to the methodology. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index.

We stated in the CY 2021 ESRD PPS final rule that we believed a 5 percent cap on the overall decrease in an ESRD facility's wage index value would be an appropriate transition, as it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. With respect to extending the transition period for at least 3 years, we stated that we believed this would undermine the goal of the wage index policy, which is to improve the accuracy of payments under the ESRD PPS, and would serve to further delay improving the accuracy of the ESRD PPS by continuing to pay certain ESRD facilities more than their wage data suggest is appropriate. We also stated that the transition policies are not intended to curtail the positive impacts of certain wage index changes, so it would not be appropriate to also apply the 5 percent cap on wage index increases. We acknowledged that a transition policy was necessary to help mitigate initial significant negative impacts from revised OMB delineations, but expressed that this mitigation must be balanced against the importance of ensuring accurate payments. We finalized the transition policy for CY 2021 as proposed. We did not propose to extend the transition policy for CY 2022 or future years, however, as we discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), we received comments acknowledging and supporting the final phase-in of the updated OMB delineations for CY 2022.

Based on our past wage index transition policies and public comments, we recognize that certain changes to our wage index policy may significantly affect Medicare payments to ESRD facilities. Commenters have raised concerns about scenarios in which changes to wage index policy may have significant negative impacts on ESRD facilities. Therefore, we considered for this CY 2023 ESRD PPS proposed rule how best to address those scenarios.

In the past, we have established transition policies of limited duration to phase in significant changes to labor market areas, such as revised OMB delineations. In taking this approach in the past, we sought to mitigate short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. In accordance with the ESRD PPS wage index regulations at § 413.231(a), we adjust the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index that is established by CMS, and which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Our policy is generally to use the most current hospital wage data and analysis available in order to ensure the accuracy of the ESRD PPS wage index, in accordance with § 413.196(d)(2). As discussed earlier in this section of the proposed rule, we believe that past wage index transition policies have helped mitigate initial significant negative impacts from changes such as revised OMB delineations. However, we recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain ESRD facilities even when labor market areas do not change as a result of revised OMB delineations. In addition, year-to-year fluctuations in an area's wage index can occur due to external factors beyond an ESRD facility's control, such as the COVID–19 PHE, and for an individual ESRD facility, these fluctuations can be difficult to predict. While we have maintained that temporary transition policies provide sufficient time for facilities to make operational changes for future CYs and have noted separate agency actions to address certain external factors, such as the issuance of waivers and flexibilities during the COVID–19 PHE (85 FR 71435), we also recognize that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations.

In light of these considerations, we are proposing a permanent mitigation policy to smooth the impact of year-to-year changes in ESRD PPS payments related to decreases in the ESRD PPS wage index. We are proposing a policy that we believe would increase the predictability of ESRD PPS payments for ESRD facilities; mitigate instability and significant negative impacts to ESRD facilities resulting from changes to the wage index; and use the most current data to maintain the accuracy of the ESRD PPS wage index.

As previously discussed, we believe our transition policy that applied a 5-percent cap on wage index decreases for CY 2021 provided greater transparency and was administratively less complex than prior transition methodologies. In addition, we believe this methodology mitigated short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. Lastly, we believe the 5-percent cap we applied to all wage index decreases for CY 2021 provided an adequate safeguard against significant and unpredictable payment reductions in that year, related to the adoption of the revised OMB delineations. However, as discussed earlier in this section of the proposed rule, we recognize there are circumstances that a 2-year transition policy, like the one adopted for CY 2021, would not effectively address for future years in which ESRD facilities continue to be negatively affected by significant wage index decreases. We believe our proposed permanent policy would eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside ESRD facilities' control (for example, public health or other emergencies, or the adoption of future OMB revisions to the CBSA delineations through rulemaking).

Typical year-to-year variation in the ESRD PPS wage index has historically been within 5 percent, and we expect this will continue to be the case in future years. Because ESRD facilities are usually experienced with this level of wage index fluctuation, we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in ESRD PPS payments due to any significant wage index decreases that may affect ESRD facilities in a year. Therefore, we believe this approach would address concerns about instability that commenters raised in response to the CY 2021 ESRD PPS proposed rule. In addition, we believe that applying a 5-percent cap on all wage index decreases would support increased predictability about ESRD PPS payments for ESRD facilities, enabling them to more effectively budget and plan their operations. Lastly, because applying a 5-percent cap on all wage index decreases would represent a small overall impact on the labor market area wage index system, we believe it would still ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. With a permanent cap, we would be able to continue to update the wage index with the most current hospital wage data as required under § 413.196(d)(2) in order to more accurately align the use of labor resources with ESRD PPS payment while mitigating the instability in payments to individual ESRD facilities that such updates may otherwise cause. As discussed in section II.B.1.d(2) of this proposed rule, we compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS

base rate. As discussed in further detail in that section, we estimate that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for CY 2023, and therefore would have a small effect on the ESRD PPS base rate. This small effect on budget neutrality also demonstrates that this policy would have a minimal impact on the ESRD PPS wage index overall. The wage index [3] is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average. Therefore, we anticipate that in the absence of any proposed wage index policy changes such as changes to OMB delineations, most ESRD facilities would not experience year-to-year wage index declines greater than 5 percent in any given year. Therefore, we anticipate that the impact to the wage index budget neutrality factor in future years would continue to be minimal. We also believe that when the 5-percent cap would be applied under this proposed policy, it likely would be applied similarly to all ESRD facilities in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) would be similar. While this proposed policy may result in ESRD facilities in a CBSA receiving a higher wage index than others in the same area (such as in situations when OMB delineations change), we believe the impact would be temporary, as the average hourly wage of facilities in a labor market would tend to converge to the mean average hourly wage of the CBSA.

As noted previously in this section of the proposed rule, 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. Under our regulations at § 413.231(a), we must use an appropriate wage index to adjust the labor-related portion of the base rate to account for geographic differences in the area wage levels. For the reasons discussed in this section of the proposed rule, we believe a 5-percent cap on wage index decreases would be appropriate for the ESRD PPS. Therefore, for CY 2023 and subsequent years, we are proposing to apply a 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we are proposing that an ESRD facility's wage index for CY 2023 would not be less than 95 percent of its final wage index for CY 2022, regardless of whether the ESRD facility is part of an updated CBSA, and that for subsequent years, an ESRD facility's wage index would not be less than 95 percent of its wage index calculated in the prior CY. This also would mean that if an ESRD facility's prior CY wage index is calculated with the application of the 5-percent cap, the following year's wage index would not be less than 95 percent of the ESRD facility's capped wage index in the prior CY. For example, if an ESRD facility's wage index for CY 2023 is calculated with the application of the 5-percent cap, then its wage index for CY 2024 would not be less than 95 percent of its capped wage index in CY 2023. Lastly, we are proposing that a newly opened or newly certified ESRD facility would be paid the wage index for the area in which it is geographically located for its first full or partial CY with no cap applied, because a new ESRD facility would not have a wage index in the prior CY. We would reflect the proposed permanent cap on wage index decreases in our regulations at § 413.231(c).

As previously discussed in this proposed rule, we believe this proposed mitigation policy would maintain the ESRD PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increase predictability of ESRD PPS payments for ESRD facilities, and mitigate instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. In section VII.D.5 of this proposed rule, we estimate the impact to payments for ESRD facilities in CY 2023 based on this proposed policy. We also note that we would examine the effects of this proposed policy, if finalized, on an ongoing basis in the future in order to assess its continued appropriateness.

(3) Proposed Update to ESRD PPS Wage Index Floor

(a) Background

A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico; however, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a policy to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015, resulting in a wage index floor of 0.4500 and 0.4000, respectively.

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

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

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

[3] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/wageindex#:~:text=A%20labor%20market%20area's%20wage,portion%20of%20the%20standardized%20amounts.*

maintain budget neutrality for wage index updates.

In the CY 2019 ESRD PPS proposed rule (83 FR 34328 through 34330), we proposed to increase the wage index floor from 0.4000 to 0.5000. We conducted various analyses to support our proposal to increase the wage index floor from 0.4000 to 0.5000. We calculated alternative wage indexes for Puerto Rico that combined labor quantities, that is FTEs, from cost reports with BLS wage information to create two regular Laspeyres price indexes [4] (ranging between 0.510 and 0.550). We discuss this analysis in detail in the following paragraphs, however, the complete discussion can be found in the CY 2019 ESRD PPS proposed rule at 83 FR 34328 through 34330.

In response to the CY 2019 wage index floor proposal, we received several comments. One commenter opposed the proposal and expressed concern over the data sources used to develop the wage indexes in general. This commenter requested additional documentation of our analysis to determine the two alternative wage indices for Puerto Rico. Several commenters expressed support for the proposal to increase the wage index from 0.40 in 2018 to 0.50 for CY 2019 and subsequent years, because they believed it would assist ESRD facilities in providing access to high-quality care particularly in rural areas where access challenges may be present. Some commenters expressed support for CMS's position that the then-current wage index floor was too low; however, they recommended CMS set the wage index floor higher than 0.5000 (specifically, at 0.5936, which was identified as the lower boundary of CMS's statistical outlier analysis as discussed further in this section of the proposed rule).

In response to these comments, in the CY 2019 ESRD PPS final rule (83 FR 56967), we stated that we continued to believe that a wage index floor of 0.5000 struck an appropriate balance between providing additional payments to areas that fell below the wage floor while minimizing the impact on the ESRD PPS base rate. We noted that the purpose of the wage index adjustment is to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located. While a wage index floor of 0.5000 continued to be the lowest wage index nationwide, we noted that the areas subject to the floor continued to have the lowest wages compared to mainland facilities. We noted that the increase to the wage index floor to 0.5000 was a 25 percent increase over the then-current floor and would provide a higher wage index for all facilities in Puerto Rico where wage indexes, based on hospital reported data, range from .3300 to .4400. For these reasons, we stated that we believed a wage index floor of 0.5000 was appropriate and would support labor costs in low wage areas.

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

As noted previously in this proposed rule, 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. The wage index floor of 0.5000 has been in effect since January 1, 2019.

We did not include any wage index floor proposals in the CY 2022 ESRD PPS proposed rule, however, we received several public comments regarding the wage index floor. As discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), three commenters, including a large dialysis organization, a non-profit health insurance organization in Puerto Rico, and a healthcare group in Puerto Rico, commented on the wage index for ESRD facilities located in Puerto Rico. These commenters recommended that CMS increase the wage index floor from 0.5000 to 0.5500, noting that in the CY 2019 ESRD PPS proposed rule, CMS reported that its own analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. They noted that CMS further stated that any wage index values less than 0.5936 are considered outlier values. They also pointed out that CMS still finalized a floor at 0.5000 and that we characterized it as a balance between providing additional payments to affected areas while minimizing the impact on the ESRD PPS base rate. Another commenter recommended that CMS evaluate policy inequities between the ESRD PPS wage index for ESRD facilities located in Puerto Rico compared to other states and territories, taking into consideration the unique circumstances that affect Puerto Rico, including its shortage of healthcare specialists and labor work force, remote geography, transportation and freighting costs, drug pricing, and lack of transitional care services.

In response to these comments, we stated in the CY 2022 ESRD PPS final rule that we would not finalize any changes to those policies since we did not propose any changes to the wage index floor or wage index methodology for CY 2022, but would take these suggestions into account when considering future rulemaking.

(b) Wage Index Floor Proposal

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. Based on this authority, we believe a proposal to increase the wage index floor would be in accordance with the Secretary's efforts to account for geographic differences in an area's 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.

For CY 2023 and subsequent years, we are proposing to increase the wage index floor to 0.6000. We believe that this wage floor increase would be responsive to comments from interested parties, safeguard access to care in areas at the lowest end of the current wage index distribution, and be supported by data and analyses that support a higher wage index floor, as discussed in the following subsections.

(i) Analysis of Puerto Rico Cost Reports for the CY 2019 ESRD PPS Rulemaking

For the CY 2019 ESRD PPS proposed rule (83 FR 34329 through 34330), we performed an analysis using ESRD facility cost reports and wage information specific to Puerto Rico from the BLS (*https://www.bls.gov/oes/2015/may/oes_pr.htm*). The analysis utilized data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015.

Using these data, we calculated alternative wage indexes for Puerto Rico that combined labor quantities, that is FTEs, from cost reports with BLS wage

[4] A Laspeyres index is an index formula used in price statistics for measuring price development of the basket of goods and services consumed in the base period (*https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Laspeyres_price_index#:~:text=The%20Laspeyres%20price%20index%20is,cost%20in%20the%20current%20period.*)

information to create two regular Laspeyres price indexes. In the context of this analysis, a Laspeyres price index can be viewed as a relative, weighted average wage of labor in each geographical area. This average combines the wages of various labor categories according to certain weights. The two indexes we considered used the same BLS-derived wages but different weights. The first index used quantity weights derived from the overall U.S. use of labor inputs. The second index used quantity weights derived from the Puerto Rico use of labor inputs. The alternative wage indexes derived from the analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. As noted earlier in this section of this proposed rule and discussed in the CY 2019 ESRD PPS final rule (83 FR 56967), commenters have noted that both of these values are above the current wage index floor and suggest that the current 0.5000 wage index floor may be too low. Commenters pointed out CMS's analysis shows that Puerto Rico's wage index likely lies between 0.51 and 0.55, while additional analyses note that any wage index values less than 0.5936 are considered outlier values, with 0.5936 therefore as the lower wage index boundary. They expressed concern that in the CY 2019 ESRD PPS proposed rule CMS proposed a new floor of only 0.5000 even though the present methodology applied to Puerto Rico has created the only outlier in the U.S. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56967), at that time, we believed that a wage index floor of 0.5000 struck an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. At the time, we conducted analyses to gauge the appropriateness of the then-current wage index floor of 0.4000 and determine whether it was too low. We did not propose to use these analyses to determine the exact value for a new wage index floor.

Specifically, as we explained in the CY 2019 ESRD PPS final rule, CMS performed a statistical outlier analysis to identify the upper and lower boundaries of the distribution of the current wage index values and remove outlier values at the edges of the distribution. In the general sense, an outlier is an observation that lies outside a defined range from other values in a population. In this case, the population of values is the various wage indexes within the CY 2019 wage index. The lower and upper quartiles (the 25th and 75th percentiles) are also used. The lower quartile is Q1 and the upper quartile is Q3. The difference (Q3 − Q1) is called the interquartile range (IQR). The IQR is used in calculating the inner and outer fences of a data set. The inner fences are needed for identifying mild outlier values in the edges of the distribution of a data set. Any values in the data set that are outside of the inner fences are identified as an outlier. The standard multiplying value for identifying the inner fences is 1.5. First, we identified the Q1 and Q3 quartiles of the CY 2018 wage index, which are as follows: Q1 = 0.8303 and Q3 = 0.9881. Next, we identified the IQR: IQR = 0.9881 − 0.8303 = 0.1578. Finally, we identified the inner fence values as shown below. Lower inner fence: Q1 − 1.5*IQR = 0.8303 − (1.5 × 0.1578) = 0.5936. This statistical outlier analysis demonstrated that any wage index values less than 0.5936 are considered outlier values, and 0.5936 as the lower boundary also suggested that the current wage index floor could be appropriately reset at a higher level.

Based on these analyses, we finalized a wage index floor of 0.5000 in the CY 2019 ESRD PPS final rule. We continued to apply the wage index floor of 0.5000 per year through CY 2022. Although we did not propose specific policies relating to the wage index floor in the CY 2022 ESRD PPS proposed rule, commenters on that rule noted that past hurricanes and the COVID–19 PHE have created infrastructure challenges that lead to high costs of dialysis care. These commenters requested CMS increase the wage index floor. In response to comments and our continued concern regarding access, in this proposed rule, we are revisiting the CY 2019 analysis, and believe that the statistical analysis of the CY 2019 data indicated that a wage index floor as high as 0.5936 would be appropriate.

(ii) Analysis of the CY 2023 ESRD PPS Proposed Rule Analytic File

We performed an analysis to compare the impact of three options to adjust the wage index floor upward using the CY 2023 ESRD PPS proposed rule analytic file. The analytic file includes qualifying data for beneficiaries for whom a 72x claim for renal dialysis services was submitted in the outpatient file setting during CY 2021. We analyzed the impact of three options for adjustment for the wage index floor: (1) wage index floor of 0.5000 (that is, no change), (2) wage index floor of 0.5500, and (3) wage index floor of 0.6000. Specifically, we examined how these three options would potentially impact the base rate, outlier thresholds, and average payment rates for all ESRD facilities.

Among the three options, we considered the wage index floor of 0.5000 as the baseline or starting point used for comparisons. We then compared the impact on various aspects of the ESRD PPS under the alternative options using the 0.5500 and 0.6000 wage index floor.

First, we examined the potential impact on the base rate. Under the baseline (wage index value of 0.5000), the proposed base rate for CY 2023 would be $264.14. The remaining two options (0.5500 floor and 0.6000 floor) would result in a base rate of $264.11 and $264.09, respectively. These options would decrease the proposed ESRD PPS base rate due to the application of the budget neutrality factor for each option, however as discussed in the following paragraph, the overall impact to ESRD PPS payments would be negligible.

Next, we examined the potential impact to the outlier thresholds. Relative to the baseline (wage index floor value of 0.5000), all options would have little or no impact on either the outlier MAP or the FDL. Lastly, we examined the potential impact to overall ESRD facility payments. After accounting for all payment adjustments under the ESRD PPS and applying the required budget neutrality factor for each option, all options would be associated with a 3.00 percent increase in projected payments for CY 2023 due to the proposed market basket update and proposed outlier FDL and MAP amounts. We estimate that the change in overall payments attributable to increasing the wage index floor would be less than 0.01 percentage point. However, we estimate that there would be a significant increase in payments to ESRD facilities located in Puerto Rico. Under the 0.5500 wage index floor option, we estimate that payments to ESRD facilities in Puerto Rico would increase by approximately 3.8 percent relative to the 0.5000 wage index floor option. Under the 0.6000 wage index floor option, we estimate that payments to Puerto Rico facilities would increase by approximately 7.6 percent relative to the 0.5000 floor. In other words, increasing the wage index floor to 0.6000 would maximize the positive impacts for ESRD facilities located in Puerto Rico while continuing to minimize the impact to overall ESRD PPS payments.

As noted previously in this section of the proposed rule, the statistical analysis presented in the CY 2019 ESRD PPS rulemaking resulted in values for the lower and upper fences for

appropriate wage index values (lower = 0.5936, upper = 0.7514). Any values in the data set that are outside of the fences are identified as an outlier. Therefore, the analysis indicated that a wage index floor of 0.5936 would be appropriate, because any wage index values less than 0.5936 or greater than 0.7514 would be considered outlier values, and a wage index value within the fences could be appropriate. For greater simplicity and public understanding, we propose to round the lower fence of 0.5936 to the nearest 0.05, to align with the increment of change that we previously adopted in the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117) for historical reductions to the ESRD PPS wage index floor. As a result, after rounding to the nearest 0.05, a wage index floor of 0.6000 would be in line with the data.

We strive for a wage index floor value that maintains the accuracy of payments under the ESRD PPS, that is, has minimal impact on the base rate, outlier thresholds, and average payment rates for all ESRD facilities. Based on our analysis of several options using the most recent analytic file for this proposed rule, a value near the lower fence of 0.5936 as described in the prior paragraph would maximize the positive impacts for ESRD facilities with wage indexes below the floor while continuing to minimize the impact to overall ESRD PPS payments.

(iii) Wage Index Floor Proposed Action

Based on our re-evaluation the CY 2019 analysis and subsequent analysis of several options using the most recent analytic file for this proposed rule, we are proposing to increase the wage index floor to 0.6000. We believe our analyses support that wage index floor value and would strike the right balance between providing increased payment to areas to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicate, while maintaining the accuracy of payments under the ESRD PPS and minimizing the overall impact to all ESRD facilities. In addition, we are proposing to amend § 413.231 by adding new paragraph (d) to reflect this change and to codify the wage index floor policy. We believe this proposed increase from the current 0.5000 wage index floor value would minimize the impact to the base rate while providing increased payment to areas that need it.

Currently, only rural Puerto Rico and 8 urban CBSAs in Puerto Rico receive the wage index floor of 0.5000. The next lowest wage index is the Virgin Islands CBSA with a value of 0.6004. Under this proposal, all CBSAs in Puerto Rico would be subject to the wage index floor of 0.6000. Though the proposed wage index floor value currently would only affect areas in Puerto Rico, we note that, consistent with our established policy, the proposed wage index floor value of 6.000 that would be applicable for any area that may fall below the floor.

We solicit comment on the proposal to increase the wage index floor from 0.5000 to 0.6000.

c. Proposed CY 2023 Update to the Outlier Policy

(1) Background

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 and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services. (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) renal dialysis equipment and supplies, 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.[5]

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS 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 ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[6] 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. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 in order to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure 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 MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this proposed rule in order to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on

[5] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[6] Transmittal 2033 issued August 20, 2010, was 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. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD 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 codified in § 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. We discuss the details of our current methodology for calculating the MAP and FDL amounts in the following section.

(2) Overview of Current Outlier Methodology

We update the national adjusted average MAP amounts and FDL amounts each year using the latest available data in the annual regulatory updates to the ESRD PPS, in accordance with our longstanding policy (75 FR 49174). As noted earlier in this section of the proposed rule, based on our longstanding policy finalized in the CY 2011 ESRD PPS final rule (75 FR 49139 through 49140), the national adjusted average MAP amounts represent the national average estimated expenditure per treatment for ESRD outlier services, adjusted by a standardization factor. As detailed in the following paragraph, when evaluating outlier eligibility for a particular patient treated in a particular facility for a particular month, this national adjusted average is further adjusted to reflect the patient-specific case-mix severity and facility characteristics. We refer to this further adjusted MAP amount as the predicted MAP amount. Unlike the national average outlier MAP amount per treatment, the predicted MAP amount varies across patients (and even across patient-months). The national adjusted average 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).

Under the methodology finalized in the CY 2011 ESRD PPS final rule (75 FR 49174), each year, using the latest available ESRD PPS data, we compute the national average MAP amount, and establish the FDL amount at a level that results in projected outlier payments that equal 1.0 percent of total payments under the ESRD PPS. When setting the outlier thresholds for the ESRD PPS rule, we first identify all ESRD outlier services for all beneficiaries using the most recently complete 72x claims data, which is claims from two years prior. For example, for the CY 2022 ESRD PPS rulemaking (86 FR 61882), we used 2020 claims. For items billed using HCPCS codes, we include injectable drugs as eligible ESRD outlier services if they belong to one of the ESRD PPS functional categories but are not in one of the composite rate drug categories (both are described in Chapter 11, Section 20.3 of the Medicare Benefit Policy Manual).[7] We do not include composite rate items because they are not eligible for outlier payments, in accordance with our longstanding ESRD PPS policy of including only formerly separately billable items and services as eligible ESRD outlier services (75 FR 49138). For items billed using National Drug Codes (NDCs), we include all oral drugs included on the ESRD outlier services list, which includes oral calcimimetics (starting January 1, 2021), and oral vitamin D analogs. We also include laboratory services that are on the list of eligible ESRD outlier services published by CMS.[8] Two supply HCPCS codes are eligible for outlier payments (A4657 syringe and A4913 miscellaneous supplies).

(a) Methodology for Calculating Imputed MAP Amounts and Predicted MAP Amounts

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49142), the ESRD facility must identify all ESRD outlier services furnished to the patient by line item on the monthly claim that it submits to Medicare in order to receive the outlier payment adjustment. We estimate the imputed MAP amount for these services by applying the established pricing methodologies described in the following paragraph of this proposed rule. The imputed MAP amounts for each of these services are summed and divided by the corresponding number of treatments identified on the claim to yield the imputed ESRD outlier services MAP amount per treatment.

We multiply the utilization (that is, units of ESRD outlier services reported on the 72X claim) with prices to obtain the outlier-eligible amount. We obtain the utilization only from claim lines that are fully covered by Medicare (that is, claim lines that do not include any non-covered charge amount) containing ESRD outlier services. Separately billable services that are performed in the ESRD facility during dialysis that are not related to the treatment of ESRD are not included in the outlier-eligible amount. In the CY 2011 ESRD PPS final rule (75 FR 49142), we finalized the basis for estimating imputed MAP amounts as follows. For pricing of ESRD outlier services that are Part B renal dialysis drugs reported with HCPCS codes, we use the latest Average Sales Price (ASP) data, which is updated quarterly. ESRD outlier services that are renal dialysis drugs formerly covered under Part D and reported with NDCs are priced based on the national average pricing data retrieved from the Medicare Prescription Drug Plan Finder, which reflect pharmacy dispensing and administration fees. For ESRD outlier services that are laboratory tests billed using HCPCS codes, we use the latest payment rates from the Clinical Laboratory Fee Schedule. For renal dialysis supplies used to administer ESRD outlier services Part B drugs (for example, syringes), we estimate MAP amounts based on the predetermined fees that apply to these items, that is, we pay $0.50 for each syringe identified on an ESRD facility's claims form. For other medical/surgical supplies such as intravenous sets and gloves, the Medicare Claims Processing Manual currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug Topics Red Book, Med-Span, or First Data Bank

[7] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

[8] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.*

(CMS Pub. 100–04, Chapter 8, § 60.2.1). We sum up the outlier-eligible amounts for drugs, laboratory tests, and supplies separately.

Next, we inflate the outlier-eligible amounts calculated for drugs, laboratory tests, and supplies from the latest available prices to forecasted prices for the rule year.[9] For example, in the CY 2022 ESRD PPS rulemaking (86 FR 61882), we used 2021 prices inflated to the forecasted prices for CY 2022. Then, we add the inflated drug, laboratory test, and supply amounts and multiply the total amount by 0.98, in accordance with the budget neutrality requirement under section 153(b) of MIPPA. Lastly, we divide the amount by the number of treatments reported on the claim in order to obtain imputed MAP amount per treatment.

After calculating the imputed MAP amount per treatment, we then compute the predicted MAP amount for the claim. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the patient-specific predicted MAP amount is equal to the national adjusted average MAP amount multiplied by the patient-specific case-mix adjusters. The national average MAP amount is adjusted by applying a standardization factor that reflects the national average of patients' outlier services case-mix severity. We apply this standardization factor in order to avoid systematically biasing the national average MAP amount calculation, which would result in setting the FDL amounts at a level that is too low. By applying the standardization factor to the national average MAP amount when calculating the patient-specific predicted MAP amount, we ensure that total imputed MAP dollars equal total predicted MAP dollars. The methodology for calculating this standardization factor is discussed in detail in the following section.

(b) Methodology for Calculating Case-Mix Standardization Factor and National Adjusted Average MAP Amount

We publish the national adjusted average MAP amount each year in the ESRD PPS proposed and final rule along with the adjustment factor. We currently use the ESRD outlier services multipliers that are the separately billable (SB) multipliers developed from the regression analysis used in the CY 2016 ESRD PPS refinement (80 FR 68993 and 80 FR 69002). As discussed in the CY 2016 ESRD PPS final rule (80 FR 68970), in accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. We revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. There was no change in the ESRD PPS outlier methodology for CY 2016, however, we updated the ESRD outlier services multipliers (80 FR 69008). The current ESRD outlier services multipliers are presented in Tables 10 and 11 in this section. A more detailed description of the steps is provided in the following paragraphs.

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TABLE 10: Adult Outlier Services Multipliers

Variable	Outlier Services Multipliers
Age	
18-44	1.044
45-59	1.000
60-69	1.005
70-79	1.000
80+	0.961
Body surface area (BSA) (per 0.1 m^2)	1.000
Underweight (BMI < 18.5)	1.090
Time since onset of renal dialysis < 4 months	1.409
Facility low volume status	0.955
Comorbidities	
Pericarditis (acute)	1.209
Gastro-intestinal tract bleeding (acute)	1.426
Bacterial pneumonia (acute)	---
Hereditary hemolytic or sickle cell anemia (chronic)	1.999
Myelodysplastic syndrome (chronic)	1.494
Monoclonal gammopathy (chronic)	---
Rural	0.978

[9] We use a blended 4-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the rule year. We inflate laboratory test prices to the rule year based on the estimated change in payment rates under the Clinical Laboratory Fee Schedule, using a CPI forecast to estimate changes for years in which a new survey will be implemented. For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor.

TABLE 11: Pediatric Outlier Services Multipliers

Patient Characteristics		Outlier Services Multipliers		
Age	Modality	Population%	Separately Billable Multiplier	Expanded Bundle Payment Multiplier
<13	PD	27.62%	0.410	1.063
<13	HD	19.23%	1.406	1.306
13-17	PD	20.19%	0.569	1.102
13-17	HD	32.96%	1.494	1.327

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As discussed in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49140), in order to calculate the predicted MAP amount per treatment, we first compute the weighted mean of the imputed MAP amounts per treatment, separately for adult and pediatric patients, at the national level. Then, for each claim, we identify the patient's case-mix adjustments that are applicable for the month based on conditions recorded on the 72x claims, and multiply all applicable ESRD outlier services multipliers together to obtain the combined ESRD outlier services multiplier. For pediatric patients, the ESRD outlier services multipliers are the age and modality adjusters; for adults, the ESRD outlier services multipliers include all case-mix and facility-level adjusters. We then calculate the national per-treatment weighted mean of the combined outlier services multipliers for adult and pediatric patients separately. We calculate one standardization factor for adult patients and one for pediatric patients. Each standardization factor is calculated as follows:

1/(weighted mean of the combined outlier services multipliers).

We calculate the adjusted national average outlier MAP amount per treatment by multiplying the per-treatment weighted mean of the imputed outlier MAP amount per treatment by the standardization factor, separately for adults and pediatric patients.

In order to calculate the predicted outlier MAP amount per treatment for each claim, we multiply the national adjusted average MAP amount per treatment, separate for adults and pediatrics, by all applicable outlier services multipliers for that claim.

(c) Methodology for Calculating FDL Amounts

In accordance with our longstanding methodology, FDL amounts are calculated separately for adult and pediatric patients so that projected outlier payments equal 1.0 percent of total ESRD PPS payments (75 FR 49142 through 49144). For the FDL amounts, we begin by computing total payments for the particular rule year separately for adults and pediatric patients. We include all anticipated updates such as the wage index, market basket update, and productivity adjustment. For each claim, we compute:

Outlier payment per Treatment = Outlier loss share amount * (Imputed MAP amount per Treatment − (Threshold per Treatment)) =
0.8 * (Imputed MAP amount per Treatment − (Predicted MAP amount per Treatment + FDL))

A claim is eligible for an outlier payment if the imputed MAP amount per treatment − (Threshold per Treatment) >0.

We simulate total outlier payments, separately for adult and pediatric patients, starting with the prior rule year's FDL amounts. If the sum of projected outlier payments for the particular rule year is higher than 1.0 percent of total payments, we increase the FDL amounts in order to decrease the amount of outlier payments. In contrast, if projected outlier payments are lower than 1.0 percent of total payments, we decrease the FDL amounts in order to increase the amount of outlier payments. We determine the separate adult and pediatric FDL amounts that bring projected adult and pediatric outlier payments to 1.0 percent of total payments for each patient population. We announce the proposed and final MAP amounts and FDL amounts in the annual ESRD PPS proposed and final rules, respectively.

(d) Example of Outlier Calculation

The following is an example of the calculation of the outlier payment. John, a 68-year-old male Medicare beneficiary, is 187.96 cm. in height and weighs 95 kg. John receives hemodialysis 3 times weekly. In January 2022, he was hospitalized for 4 days for a compound ankle fracture. During the hospitalization John did not undergo any dialysis treatments. After discharge John resumed his dialysis treatments, but required additional laboratory testing and above-average doses of several injectable drugs, particularly EPO, to return his hemoglobin levels to the normal range. During January 2022, John received 9 hemodialysis treatments at his usual ESRD facility. The facility submitted a claim for eligible ESRD outlier services including drugs and biological products, laboratory tests, and supplies totaling $3,000.00.

We begin by computing the predicted MAP amount per treatment based on the ESRD outlier services case-mix adjustment factors applicable to John. These factors are age and BSA. John's BSA is 2.2161. Applying the ESRD outlier services multiplier set forth in Table 10 of this proposed rule for BSA, John's ESRD outlier services payment multiplier (PM) for BSA is computed as follows:

$1.000^{(2.2161-1.9)/0.1} = 1.000^{3.16135} = 1.000$

Using this calculated PM for BSA and the PM for age from Table 10, John's outlier services PM is calculated as:

1.005 * 1.000 = 1.005

For CY 2022, the national average MAP amount per treatment for adult patients is $42.75. Therefore, the predicted MAP amount per treatment for John is: $42.75 * 1.005 = $42.96.

Next, we determine the imputed MAP amount per treatment which reflects the estimated expenditure for ESRD outlier services incurred by the ESRD facility. John's imputed MAP amount per treatment is equal to the total amount of

drugs and biological products, laboratory tests, and supplies submitted on the claim, divided by the number of treatments. We calculate this as: $3000.00/9 = $333.33.

Next, we must determine if John's ESRD facility is entitled to outlier payments for John's January claim by comparing the predicted MAP amount to the threshold per treatment. We calculate the threshold per treatment by adding the CY 2022 FDL amount to the predicted MAP amount for John.

The threshold amount for John is calculated to reflect the case-mix adjustments for age and BSA.

Threshold = Predicted MAP amount ($42.96) + FDL ($75.39) = $118.35

Because John's imputed MAP amount per treatment was $333.33, which exceeds the sum of the predicted MAP amount and FDL amount ($118.35), John's ESRD facility is eligible for outlier payments.

The outlier payments for John's 9 treatments are calculated as the amount by which the imputed MAP amount exceeds the threshold, then multiplied by the 80 percent loss-sharing ratio.

Imputed MAP amount minus Threshold: $333.33 − $118.35 = $214.98

Outlier payments per treatment: $214.98 * .80 = $171.98

Total outlier payments: $171.98 * 9 = $1,547.82

(3) Current Issue and Concerns From Interested Parties

For several years, outlier payments have consistently landed below the target of 1.0 percent of total ESRD PPS payments. Commenters have raised concerns that the methodology we currently use to calculate the outlier payment adjustment results in underpayment to ESRD facilities, as money was removed from the base rate to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). Therefore, they have urged us to adopt an alternative modeling approach that accounts for declining trends in spending for eligible ESRD outlier services over time.

MedPAC echoed these concerns in a comment in response to the CY 2021 ESRD PPS proposed rule (85 71438 through 71440), and also suggested that the introduction of calcimimetics as an eligible ESRD outlier service could perpetuate this issue. MedPAC predicted that if calcimimetic use decreases between 2019 (when the products were paid under the ESRD PPS using the TDAPA) and 2021 (when the products would be paid as part of the ESRD PPS base rate), the outlier threshold would be set too high, and outlier payments would be lower than the target of 1.0 percent of total CY 2021 payments.

In response to the concerns raised by MedPAC and others, CMS has been conducting research in conjunction with its contractor, including holding three technical expert panels (TEPs), to investigate possible improvements to the ESRD PPS payment methodologies. As discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36401 through 36402), during the second and third TEP meetings convened by the CMS contractor in 2019 and 2020, panelists discussed their specific concerns regarding the current outlier policy and alternative methodologies to achieve the 1.0 percent outlier target. Some TEP panelists and interested parties have strongly advocated that we establish a new outlier methodology using alternative modeling approaches that account for trends in formerly separately billable spending over time. Other interested parties advocated for changing the outlier percentage. Overall, panelists expressed support for any change to outlier calculations that result in total outlier payments being closer to the target.

In the CY 2022 ESRD PPS proposed rule (86 FR 36402), we stated that we were considering potential revisions to the calculation of the outlier threshold to address concerns from interested parties. In that rule, we presented the information that was previously provided to the TEP in order to solicit comments from interested parties in the dialysis community and the public (86 FR 36402). We published an RFI to solicit comments on the approaches noted in the previous paragraph and any information that would better inform future modifications to the methodology (86 FR 36402). In addition to generally seeking input regarding calculating the outlier payment adjustment, we specifically requested responses to the following questions:

- An alternative approach could be to estimate the retrospective FDL trend by using historical utilization data. How many years of data should be included in calculation of this trend to best capture changes in treatment patterns?
- The simulation of the FDL can be improved by better anticipating changes in utilization of ESRD outlier services. What are the factors that affect the use of ESRD outlier services over time, and to what extent should CMS try to forecast the effect of these factors?
- As ESRD beneficiaries can now choose to enroll in Medicare Advantage (MA), please describe any anticipated effects of this enrollment change on the use of ESRD outlier services in the ESRD PPS.
- Adoption of the suggested methodology may account for systematic changes in the use of high cost outlier items. However, inherently unpredictable changes may still push the outlier payment off the 1.0 percent target. Please comment on the acceptability of the following payment adjustment methods: Payment reconciliation in the form of an add-on payment adjustment or a payment reduction might be necessary to bring payments in line with the 1 percent target. An add-on payment adjustment would be distributed after sufficient data reveal the magnitude of the deviation (1 year after the end of the payment year). The distribution of these monies could be done via a lump sum or via a per-treatment payment add-on effective for 1 year. This add-on payment adjustment would be paid irrespective of the outlier claim status in that year. A payment reduction could take the form of a reduction in the base rate, also to be applied 1 year after the end of the payment year.

As discussed in the CY 2022 ESRD PPS final rule (86 FR 61996), we received numerous public comments in response to our RFI on payment reform under the ESRD PPS. As discussed in a more detailed comment summary on the CMS website,[10] we received comments from major national patient and provider organizations and MedPAC on the RFI regarding the outlier policy. Commenters reiterated their concerns that outlier payments under the ESRD PPS have not achieved the 1.0 percent target since the system was implemented. Commenters focused on three main suggestions for the outlier policy: (1) reducing the target outlier percentage to 0.5 or 0.6 percent, which commenters argued would more closely align with the historical percentage that has been paid under the ESRD PPS; (2) changing the methodology used to calculate the FDL and MAP amounts in order to better account for not only historical trends in utilization but also changes in prices and utilization of new and innovative products; and (3) re-allocating money from the ESRD PPS that is not paid out for outliers—either by allowing unspent funds to apply to a subsequent year's withhold amount or establishing a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities.

[10] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

(4) Proposed Changes to the Outlier Methodology for CY 2023

In response to significant public comments received over many years, we are proposing changes to the outlier policy for CY 2023 and subsequent years. In developing these proposed changes, we considered the three main suggestions that commenters raised in response to the CY 2022 RFI.

First, we considered the recommendation from commenters that CMS reduce the outlier percentage from 1.0 percent to 0.5 percent or 0.6 percent. Although this approach would allow us to potentially increase payment under the ESRD PPS base rate for treatment of those patients who do not qualify for outlier payments, we are chiefly concerned that this approach would not directly address the root cause of outlier payments totaling less than 1 percent of overall ESRD PPS payments in prior years. Although reducing the target outlier percentage would reduce the size of outlier payments relative to total ESRD PPS payments, we are concerned that if we do not change the methodology that we use to prospectively determine the outlier threshold, we may continue to not meet even the lower target outlier percentage.

Additionally, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the most costly, resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We are concerned that a reduced outlier percentage may not provide the appropriate level of payment for outlier cases, and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Therefore, after careful consideration, we are not proposing to reduce the outlier percentage.

Next, we considered the recommendation to re-allocate money from the ESRD PPS that is not paid out for outliers. As explained earlier in this section of the proposed rule, we solicited comments in the CY 2022 ESRD PPS proposed rule (86 FR 36402) about a potential payment reconciliation in the form of an add-on payment adjustment or a payment reduction, which might be necessary to bring outlier payments in line with the 1.0 percent target. As we described in the detailed RFI comment summary document on the CMS website,[11] several commenters supported this idea, and recommended that CMS allow unspent outlier funds from the prior year to reduce the amount set aside for outliers in the next year. Other commenters suggested that unspent outlier funds could be used to fund initiatives that support health equity. One national dialysis organization pointed out that lags in the claims process and refiling of claims, often over different calendar years, would present challenges to such an approach. This organization noted that these challenges could make it difficult to accurately calculate the amount of the add-on payment adjustment or ''clawback'' payment amount for each year. We agree with the concerns this organization raised, and believe that these challenges would make it difficult to accurately operationalize commenters' recommendations that we allow unspent funds to apply to a subsequent year's withhold amount or establish a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities. Therefore, after careful consideration, we are not proposing to establish a payment reconciliation methodology for the ESRD PPS outlier policy.

Lastly, we considered the feedback from interested parties and commenters in the past ESRD PPS TEPs and in comments to the RFI in the CY 2022 ESRD PPS proposed rule regarding the methodology used to calculate the FDL amounts. As commenters have previously noted, the current methodology that we use to prospectively calculate the FDL amounts has not been able to effectively account for declining use of eligible ESRD outlier services (that is, separately billable items and services prior to 2011) each year since the implementation of the ESRD PPS. For example, the CY 2021 FDL amounts ($48.33 for adult and $41.04 pediatric patients) were added to the predicted MAP amounts to determine the outlier thresholds using 2019 data. The outlier MAP amount continued to fall from 2019 to 2021. Consequently, in 2021 claims, outlier payments comprised approximately 0.4 percent of total ESRD PPS payments, demonstrating that the use of 2019 data resulted in thresholds too high to achieve the targeted 1.0 percent outlier payment.

Several organizations that commented in response to the RFI[12] in the CY 2022 ESRD PPS proposed rule expressed that using a retrospective FDL trend based on historical utilization data would provide a better calculation of the appropriate prospective FDL amounts. These organizations also cautioned that such a methodology would remain sensitive to changes in utilization or price increases for new and innovative products. Commenters suggested that such a methodology would likely not succeed in estimating the appropriate FDL amounts in years when there are significant changes to the ESRD PPS, such as in years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. MedPAC suggested that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the trend over time in spending for items in the ESRD PPS bundled payment that were separately billable prior to 2011.

In the CY 2022 ESRD PPS proposed rule (86 FR 36402), we also solicited comments on any anticipated effects enrollment changes in MA plans might have on the use of ESRD outlier services. National provider organizations pointed out that to the extent that MA plans are not permitted to systematically include healthier ESRD beneficiaries and exclude costly beneficiaries, there would seem to be little impact on the outlier pool. They expressed concern about the decision[13] to eliminate network adequacy standards that apply to ESRD facilities.

[11] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

[12] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

[13] We believe the commenters were referring to a CMS decision to remove outpatient dialysis from the list of facility types subject to network adequacy standards and require that MA organizations submit an attestation that it has as an adequate network that provides the required access and availability to dialysis services, including outpatient facilities. CMS indicated in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (CMS–4190–F) final rule that we believe there is more than one way to access medically necessary dialysis care and that we wanted plans to exercise all of their options to best meet a beneficiary's health care needs. (85 FR 33796, 33852 through 33866). Further, regardless of whether a facility or provider specialty type is subject to network adequacy standards, MA organizations are required in § 422.112(a)(3) to arrange for health care services outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Section 422.112(a)(10) requires MA plans to ensure access and availability to covered services consistent with the prevailing community pattern of health care delivery in the areas served by the network. (85 FR 33858 through 33860).

They predicted these decisions would discourage many ESRD patients from enrolling in MA plans, especially those needing specialized treatment or requiring additional medications. To the extent this scenario were to occur, commenters argued that it could result in ''outlier'' patients, specifically, those sicker, costlier patients, remaining in traditional Medicare and the healthier, less costly patients enrolling in MA plans.

Based on these comments, we are proposing an approach that would account for the historical trend in spending for formerly separately billable items and services and would also effectively account for the introduction of new and innovative products under the ESRD PPS. We believe that our proposed methodology would also adapt to changes in the ESRD PPS patient population, such as the potential scenario that commenters raised in which costlier ''outlier'' patients might remain in traditional Medicare while healthier, less costly patients enroll in MA plans.

As we discussed earlier in this section of the proposed rule, our current methodology prospectively calculates the adult and pediatric FDL and MAP amounts based on simulated outlier payments. The utilization of outlier services for these simulated outlier payments comes from a single year of ESRD PPS claims, and the prices come from the pricing methodology described earlier in this section of the proposed rule using latest available prices inflated to forecasted prices for the rule year. Under the current methodology, we prospectively set the adult and pediatric FDL amounts so that simulated outlier payments for the rule year are estimated to equal 1.0 percent.

For CY 2023 and subsequent years, we are proposing to continue to calculate the adult and pediatric MAP amounts for the rule year (CY 2023) following our established methodology, but we are proposing to prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We are also proposing to adjust the calculation of the historical FDL trend for years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. We note that we are not proposing to apply this method to pediatric FDL amount calculations, as the pediatric population is too small to reliably use this method.

We are proposing the following steps for prospectively calculating the adult FDL amounts:

- *Step 1:* Use ESRD PPS claims from the 3 most recent available data years, relative to the rule year. For CY 2023, this would include data from CY 2019, CY 2020, and CY 2021. Using these claims, the projected base rate for the rule year, and the latest available prices of ESRD outlier services, we would use our established methodology to calculate the FDL amounts that would have achieved the 1.0 percent outlier target for each year. In the following steps, we refer to these calculated FDL amounts as the ''retrospective'' FDL amounts.
- *Step 2:* If any items or services that were previously paid for using the TDAPA or TPNIES in any of the 3 most recent available data years would be ESRD outlier services for the rule year, then we would also calculate an alternative series of retrospective FDL amounts. This alternative series would account for any new ESRD outlier services, that is, any ESRD outlier services for the rule year that were previously paid for using the TDAPA or TPNIES in any of the 3 most recent available data years. In the following steps, we refer to this alternative series of retrospective FDL amounts as the ''adjusted'' retrospective FDLs. Specifically, we would calculate the adjusted retrospective FDL amounts as follows:

++ If a new ESRD outlier service was paid for using the TDAPA or TPNIES in the most recent available data year, as in the case of calcimimetics in the CY 2020 data used for the CY 2022 ESRD PPS rulemaking, then we would calculate the first retrospective FDL amount for that year using the latest available prices and historical utilization of ESRD outlier services that includes TDAPA or TPNIES utilization for the new ESRD outlier service. We would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. In order to calculate the adjusted retrospective FDLs for the preceding 2 data years, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service for the most recent data year, and add this amount to each retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2021 to the retrospective FDL amounts for CY 2020 and CY 2019.

++ If a new ESRD outlier service first became eligible in the most recent available data year, as in the case of calcimimetics in the CY 2021 data used for this CY 2023 ESRD PPS proposed rule, then we would calculate the first retrospective FDL amount for the most recent data year using the latest available prices and historical utilization of ESRD outlier services. We would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. In order to calculate the adjusted retrospective FDL amounts for the preceding 2 data years, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service for the most recent data year, and add this amount to each retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2021 to the retrospective FDL amounts for CY 2020 and CY 2019.

++ If a new ESRD outlier service first became eligible in the second most recent available data year, as in the case of calcimimetics in the CY 2022 data that we would expect to use for the CY 2024 rulemaking, then we would calculate retrospective FDL amounts for the most recent two data years using the latest available prices and historical utilization of outlier services. For the earliest historical year, in which the new ESRD outlier service was still being paid for using the TDAPA or the TPNIES, we would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. In order to calculate the adjusted retrospective FDL amount for the earliest historical year, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service in the second most recent available data year, and add this amount to the retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2020 to the retrospective FDL amount for CY 2019.

++ If a new ESRD outlier service first became outlier eligible earlier than any of the 3 most recent available data years, we would not calculate any adjusted retrospective FDL amounts for that item or service. For example, for CY 2025, we would not calculate any adjusted retrospective FDL amounts to account for calcimimetics in the CY 2021, CY 2022, and CY 2023 claims. We would calculate only the series of retrospective FDL amounts for these years in accordance with Step 1.

- *Step 3:* Using either the series of retrospective FDL amounts or adjusted retrospective FDL amounts, as appropriate, for the 3 most recent available data years, we would use a

linear regression to calculate the historical trend in FDL amounts. We would project this trend forward to determine the appropriate FDL amount for the rule year.

For illustration purposes, Figure 1 presents an example of the adult retrospective FDL amounts and adjusted retrospective FDL amounts calculated for CY 2019, CY 2020, and CY 2021, as well as the projected FDL trend through CY 2023, under our proposed methodology. The adjusted retrospective FDL amounts shown in Figure 1 would account for the difference in retrospective FDL amounts calculated with and without calcimimetics, which became ESRD outlier services beginning January 1, 2021. Figure 1 illustrates how the proposed methodology would incorporate data for new ESRD outlier services while continuing to account for the downward historical trend in spending for formerly separately billable items and services.

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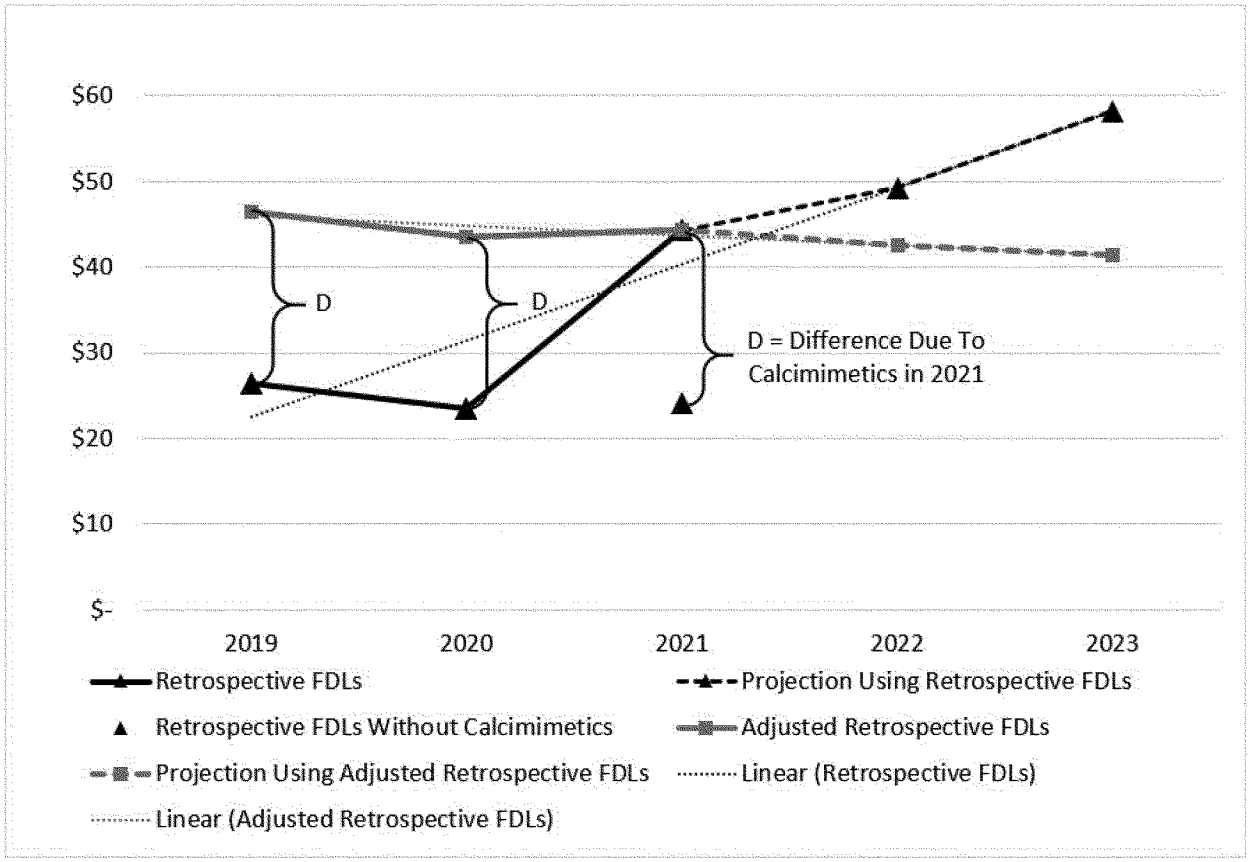
Figure 1. Proposed Retrospective FDL Amounts and Adjusted Retrospective FDL Amounts (CY 2019 through CY 2021) and Their Corresponding Projected FDLs through CY 2023 for Adults



(5) Proposed CY 2023 Update to the Outlier Services MAP Amounts and FDL Amounts

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. As discussed in the CY 2022 ESRD PPS final rule (86 FR 61883), CY 2020 claims data showed outlier payments represented approximately 0.6 percent of total payments. CY 2021 claims data show outlier payments represent approximately 0.4 percent of total payments. Accordingly, as discussed in section II.B.1.c.(4) of this proposed rule, we are proposing to change our ESRD PPS outlier methodology to better target 1.0 percent of total payments. We are proposing that the outlier services MAP amounts and pediatric FDL amounts for CY 2023 would be derived from claims data from CY 2021, consistent with our policy to base any adjustments made to the MAP amounts under the ESRD PPS upon the most recent data year available. We are proposing that the adult FDL amounts for CY 2023 would be derived from the projected FDL trend calculated according to the proposed methodology described in section II.B.1.c.(4) of this proposed rule.

The impact of this proposed update is shown in Table 12, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2022 with the updated proposed estimates for this rule. The estimates for the proposed CY 2023 MAP amounts, which are included in Column II of Table 12, were inflation adjusted to reflect projected 2023 prices for ESRD outlier services.

TABLE 12: Outlier Policy: Impact of Proposal to Use Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)*		Column II Proposed outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$ 25.91	$ 44.49	$24.19	$38.42
Adjustments				
Standardization for outlier services	1.0693	0.9805	1.0809	0.9785
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$27.15	$42.75	$25.62	$36.85
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$26.02	$75.39	$21.51	$40.75
Patient-month-facilities qualifying for outlier payment	12.89%	7.08%	13.58%	11.54%

*Column I was obtained from Column II of Table 1 from the CY 2022 ESRD PPS final rule (86 FR 61883).
**The proposed FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2019, 2020, and 2021.

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As demonstrated in Table 12, the estimated FDL per treatment that determines the CY 2023 outlier threshold amount for adults (Column II; $40.75) is lower than that used for the CY 2022 outlier policy (Column I; $75.39). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $42.75 to $36.85. For pediatric patients, there is a decrease in the FDL from $26.02 to $21.51. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $27.15 to $25.62.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2023 will be 11.54 percent for adult patients and 13.58 percent for pediatric patients, based on the 2021 claims data and proposed methodology described in section II.B.1.c.(4) of this proposed rule. 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 ESAs and other injectable drugs).

(6) 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 2021 claims, outlier payments represented approximately 0.4 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 2021 data and the proposed methodology described in section II.B.1.c.(4) of this proposed rule are expected to result in aggregate outlier payments closer to the 1 percent target in CY 2022. We believe the update to the outlier MAP and FDL amounts for CY 2023 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us closer to meeting our 1 percent outlier policy goal, because we are using more current data for computing the MAP and FDL amounts, which is more in line with current outlier services utilization rates. We also note that recalibration of the FDL amounts 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 2023 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

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

applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2023

We are proposing an ESRD PPS base rate for CY 2023 of $264.09. This proposed 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 2023, 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 2023 wage index budget-neutrality adjustment factor using treatment counts from the 2021 claims and facility-specific CY 2022 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2022. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2023. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2023 ESRD PPS wage index and proposed labor-related share for CY 2023. As discussed in section II.B.1.b of this proposed rule, the proposed ESRD PPS wage index for CY 2023 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. Additionally, as discussed in section II.B.1.b(3)(b)(iii) of this proposed rule, we are proposing to increase the ESRD PPS wage index floor from 0.5000 to 0.6000 and to apply a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. The total of these payments becomes the new CY 2023 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 2023 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2023 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 2023 proposed wage index budget-neutrality adjustment factor is 0.999997. This application would yield a CY 2023 ESRD PPS proposed base rate of $257.90 prior to the application of the market basket increase factor ($257.90 × 0.999997= $257.90). This CY 2023 proposed wage index budget-neutrality adjustment factor reflects the impact of all proposed wage index changes, including the proposed CY 2023 ESRD PPS wage index and labor-related share, proposed increase to the wage index floor, and proposed permanent 5-percent cap on wage index decreases.

For purposes of illustration and analysis, we also calculated a separate budget neutrality factor in order to estimate the impact that the proposed permanent 5-percent cap on wage index decreases would have on CY 2023 ESRD PPS payments. Following the steps described earlier in this section of the proposed rule, we divided estimated payments without the proposed 5-percent cap by estimated payments with the cap. We calculated the resulting budget neutrality factor as 0.999910. Applying this budget neutrality factor to the ESRD PPS base rate, we estimate that the proposed permanent 5-percent cap would result in a $0.02 decrease to the ESRD PPS base rate ($257.90 × 0.999910 = $257.88). The overall CY 2023 proposed wage index budget-neutrality adjustment factor is higher, because the effect on budget neutrality of the proposed 5-percent cap is offset by the effect of the proposed increase to the labor-related share.

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 2023 projection of the proposed ESRDB market basket percentage increase factor is 2.8 percent. In CY 2023, 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 in section II.B.1.a of this proposed rule, the proposed productivity adjustment for CY 2023 is 0.4 percent, thus yielding a proposed update to the base rate of 2.4 percent for CY 2023. Therefore, the proposed CY 2023 ESRD PPS base rate is $264.09 ($257.90 × 1.024 = $264.09).

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this proposed rule, we will refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 calendar years.

The proposed CY 2023 TPNIES offset amount for capital-related assets that are home dialysis machines is $9.73. As discussed previously in section II.B.1.a(3)(c) of this proposed rule, the proposed CY 2023 ESRD bundled market basket increase factor minus the productivity adjustment is 2.4 percent (2.8 percent minus 0.4 percentage point). Applying the proposed update factor of 1.024 to the CY 2022 offset amount results in the proposed CY 2023 offset amount of $9.73 ($9.50 × 1.024 = $9.73). We propose to update this calculation to use the most recent data available in the CY 2023 ESRD PPS final rule.

f. Proposed Revision to the Oral-Only Drug Definition and Clarification Regarding the ESRD PPS Functional Category Descriptions

(1) Background

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 subclause (iii) of such section states that these services include other drugs and biologicals [14] 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.

When we implemented the ESRD PPS in 2011 (75 FR 49030), we interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than 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) of the Act, 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 or biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053). In that rule we defined renal dialysis services at § 413.171 as including other drugs and biologicals 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 biologicals with only an oral form. Although we included oral-only renal dialysis service drugs and biologicals 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 ESRD PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed rule (74 FR 49929), we noted that the only oral-only drugs that we identified were phosphate binders and calcimimetics, specifically, cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. All of these drugs fall into the ESRD PPS functional category for bone and mineral metabolism. In the CY 2011 ESRD PPS final rule (75 FR 49043), we explained that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products under the ESRD PPS, 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 would be 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 coverage to continue under Medicare Part D.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only ESRD-related drugs in the ESRD PPS 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) for providing payment for oral-only renal dialysis service drugs under the ESRD PPS 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 to preclude 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, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. Similar to the CY 2014 and CY 2015 ESRD PPS final rule changes, we implemented this delay in the CY 2016 ESRD PPS final rule (80 FR 469028) 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. We stated that we continue to believe that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment and should be paid for under the ESRD PPS.

Section 217(c)(1) of PAMA required us to adopt a process for determining when oral-only drugs are no longer oral-only. In the CY 2016 ESRD PPS proposed rule (80 FR 37839), when considering a definition for the term ''oral-only drug,'' we noted that in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49039), we described oral-only drugs as those that have no injectable equivalent or other form of administration. In the CY 2016 ESRD PPS final rule (80 FR 69027), we finalized the definition of oral-only drug at § 413.234(a) to provide that an oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than an oral form. We also finalized our process at § 413.234(d) for determining that an oral only drug is no longer considered oral-only when a non-oral version of the oral-only drug is approved by FDA. We stated that we will undertake rulemaking to include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when it is no longer considered an oral-only drug under this regulation. In addition, we noted that we will pay for the existing oral-only drugs (which were, at that time, only phosphate binders and calcimimetics) using the TDAPA, as applicable. We stated that this will allow us to collect data reflecting

[14] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this CY 2023 ESRD PPS proposed rule except where referencing specific language in the Act or regulations.

current utilization of both the oral and injectable or intravenous 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 also stated that for future oral-only drugs for which a non-oral form of administration comes on the market, we will apply our drug designation process as we would for all other new drugs.

In the CY 2016 ESRD PPS final rule (80 FR 69017), we also codified the term ESRD PPS functional category at § 413.234(a) as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We explained that we codified this definition in regulation text to formalize the approach we adopted in CY 2011 because the drug designation process is dependent on the ESRD PPS functional categories (80 FR 69015). We provided a detailed discussion of how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since the implementation of the ESRD PPS (80 FR 69013 through 69015). We discussed how we grouped renal dialysis drugs and biological products into functional categories based on their action (80 FR 37831). We explained that this was done for the purpose of adding new drugs and biological products with the same function into the functional categories and the ESRD PPS bundled payment as expeditiously as possible after the drug becomes commercially available to provide access for the ESRD Medicare population (80 FR 69014). Our approach of considering drugs and biological products as included in the ESRD PPS base rate if they fit within one of our ESRD PPS functional categories is reflected in the drug designation process set forth in our regulations at § 413.234.

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027) described in the previous paragraphs, we issued a change request to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA.[15] We paid for calcimimetics using the TDAPA under the ESRD PPS for 3 years, CY 2018 through CY 2020, during which time CMS collected utilization data. In the CY 2021 ESRD PPS final rule (85 FR 71406 through 71410), we finalized a modification to the ESRD PPS base rate to account for the costs of calcimimetics following the methodology codified at § 413.234(f). Accordingly, effective January 1, 2021,[16] calcimimetics are no longer paid for using the TDAPA and instead are included in the ESRD PPS base rate. We also noted that effective January 1, 2021, calcimimetics are eligible for outlier payments as ESRD outlier services under § 413.237.[17]

At the present time, phosphate binders are still considered oral-only drugs, and therefore under current law will be paid under Medicare Part D until January 1, 2025, as long as they remain oral-only drugs. Beginning January 1, 2025, in accordance with § 413.174(f)(6), payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients will be incorporated into the ESRD PPS and separate payment will no longer be provided.

Under our current policy (80 FR 69027), if an injectable equivalent or other form of administration of phosphate binders were to be approved by FDA prior to January 1, 2025, the phosphate binders would no longer be considered oral-only drugs and would no longer be paid outside the ESRD PPS. We would pay for the oral and any non-oral version of the drug using the TDAPA under the ESRD PPS for at least 2 years, during which time we would collect and analyze utilization data. If no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025 then we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will then undertake rulemaking to modify the ESRD PPS base rate to account for the cost of the drug in the ESRD PPS bundled payment. As required by section 632(b)(1) of ATRA, as amended by section 217(a)(2) of PAMA, in establishing payment for oral-only drugs under the ESRD PPS, we will use data from the most recent year available.

(2) CMS Observations Regarding Decrease in Drug Utilization and Medicare Expenditures When Drugs Are Included in the ESRD PPS

As we prepare for the incorporation of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, we have been studying trends in drug utilization and Medicare expenditures for renal dialysis drugs and biological products. Our observations, presented below, provide further support for our longstanding view that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment and should be paid for under the ESRD PPS.

With the transition of payment for calcimimetics from Medicare Part D to Medicare Part B, we observed two distinct patterns. First, when the calcimimetics were paid for using the TDAPA under the ESRD PPS beginning 2018, we observed a significant increase in the utilization of calcimimetics across patients of all races and ethnicities, with a more significant uptake by the African-American/Black minority population. As utilization increased, cost decreased. To demonstrate, before 2018, only brand-name oral calcimimetics were available, but in 2018, generic oral calcimimetics began to enter the market. We observed a greater than ten-fold decrease in the per milligram cost of Cinacalcet, the oral calcimimetic, from Q1 2018, which was the beginning of the TDAPA period for calcimimetics, and Q4 2020. We believe that the transition of payment for calcimimetics from Part D to Part B increased access for the population that lacked Part D coverage or had less generous coverage than the Part D standard benefit. Second, after we incorporated the calcimimetics into the ESRD PPS bundled payment beginning January 1, 2021, we noted a decrease in the calcimimetic utilization overall, with a pronounced decrease in the more expensive injectable calcimimetic. In order to mitigate the risk of potential access issues for minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, we believe it is important that any future oral-only drugs that fit into a current ESRD PPS functional category be included in the ESRD bundled payment through the processes previously finalized in our regulations at § 413.234 and described in this CY 2023 ESRD PPS proposed rule.

We have noted a similar pattern in the change in utilization with other renal dialysis service drugs, such as vitamin D agents, which were separately paid

[15] 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.

[16] Change Request 12011, Transmittal 10568, issued January 14, 2021,

[17] In the CY 2020 ESRD PPS final rule (84 FR 60803), CMS made a technical change to § 413.234(a) to revise the definitions of ''ESRD PPS functional category'' and ''Oral-only drug'' to use the term ''biological product'' instead of ''biological'' for greater consistency with FDA nomenclature.

prior to the establishment of the ESRD PPS and subsequently included in the ESRD PPS bundled payment. Prior to the implementation of ESRD PPS, certain renal dialysis drugs and biological products were separately paid according to the number of units of the drug administered; in other words, the more units of a drug or biological product administered, the higher the Medicare payment.[18] Between 2011 and 2013, the first 3 years of the new ESRD PPS, the utilization of formerly separately billable renal dialysis drugs and biological products included in the ESRD PPS bundled payment declined. With the inclusion of the formerly separately billable renal dialysis drugs and biological products in the ESRD PPS bundled payment, the ESRD PPS increased the incentive for ESRD facilities to be more efficient in providing these products.

CMS has observed that incorporation of formerly separately billable renal dialysis drugs and biological products into the ESRD PPS bundled payment is followed by a decrease in utilization of the drug. For example, by drug class, on a per treatment basis, between 2007 and 2013, the use of vitamin D agents (part of the bone and mineral metabolism ESRD PPS functional category) declined by 20 percent, with most of the decline occurring between 2010 and 2013. Under the ESRD PPS, drug utilization and average sales price (ASP) data suggest increased competition between the two principal vitamin D agents in the ESRD PPS bundled payment. Between 2010 and 2014, per treatment use of paricalcitol, the costlier vitamin D drug (according to Medicare ASP data) declined, while per treatment use of doxercalciferol, the less costly vitamin D drug, increased. Between 2010 and 2015, the ASP price per unit for both these products declined by 60 percent. We have observed a similar pattern in price decline as a result of competition with the oral calcimimetics between 2018 and 2021. The brand name oral cinacalcet (a calcimimetic) was paid under Medicare Part D drug before 2018, but the price of the oral drug dropped significantly once the injectable calcimimetic became available and the oral (both brand name and generics) and the injectable calcimimetic became eligible for payment using the TDAPA under the ESRD PPS.

We have been monitoring health outcomes since 2011 and have not observed any sustained increase in adverse outcomes related to incorporation of renal dialysis drugs or biological products into the ESRD PPS bundled payment, including adverse outcomes related to changes in utilization of different forms of calcimimetics, as noted in the previous paragraph. To date, we have monitored for hospitalizations, fractures, strokes, acute myocardial infarctions, heart failures, parathyroidectomies, and calciphylaxis. Utilization of calcimimetics remains higher among minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, and we have not observed any sustained adverse health outcomes due to this change in utilization. We continue to monitor these health outcomes on an ongoing basis.

(3) CMS Observations on Part D Spending for Dialysis Drugs

While the use of formerly separately billable renal dialysis drugs included in the ESRD PPS bundled payment declined between 2011 and 2013, the use of dialysis drugs paid under Medicare Part D (as measured by Medicare spending) increased. Medicare Part D spending for oral-only drugs in 2016, which at that time only included calcimimetics and phosphate binders, grew to $2.3 billion, an increase of 22 percent per year compared with 2011. When calculated on a per treatment basis, Medicare Part D spending for dialysis drugs increased by 20 percent per year. In addition, between 2011 and 2016, total Medicare Part D spending for dialysis drugs grew more rapidly than total Medicare Part D spending for ESRD beneficiaries on dialysis (22 percent vs. 11 percent, respectively). In 2016, Medicare Part D spending for dialysis drugs constituted 60 percent of gross Medicare Part D spending for ESRD beneficiaries.

As noted previously in this section of the proposed rule, beginning on January 1, 2018, calcimimetics were paid for using the TDAPA under the ESRD PPS and beginning on January 1, 2021, were incorporated into the ESRD PPS bundled payment. Currently, phosphate binders are the only drugs that are paid for under Medicare Part D as oral-only drugs.

A number of studies, including studies by CMS, have examined trends in Medicare spending for phosphate binders. Between 2013 and 2014, Medicare Part D spending for phosphate binders increased by 24 percent to approximately $980 million. Medicare costs for phosphate binders for patients on dialysis and patients with chronic kidney disease enrolled in Medicare Part D exceeded $1.5 billion in 2015. Additionally, annual Medicare expenditures for phosphate binders increased by 118 percent (approximately $486 million) between 2008 and 2013, reflecting increasing numbers of patients on dialysis being prescribed phosphate binders and large increases in per-user phosphate binder costs. During these 6 years, total costs per user-year for phosphate binders increased 67 percent, in contrast to a 21 percent increase for all other Medicare Part D medications for patients receiving dialysis services.[19]

MedPAC has also studied Medicare spending under Part D for phosphate binders. According to MedPAC's report titled March 2021 Report to the Congress: Medicare Payment Policy [20] between 2017 and 2018, spending for phosphate binders furnished to FFS beneficiaries on dialysis declined by 17 percent to $1.1 billion. This decline is linked to FDA's approval in 2017 for a generic version of Renvela (sevelamer carbonate), a phosphate binder. By contrast, spending grew 12 percent per year for the five-year period 2012 through 2017. In 2018, Medicare Part D spending for phosphate binders accounted for 40 percent of all Medicare Part D spending for dialysis beneficiaries. The most recent CMS data through December 2020 indicates that total spending on phosphate binders is approximately $1 billion. The average spending per treatment of phosphate binders in 2020 is approximately $19.85 among all adult ESRD beneficiaries, and $24.24 among all Part D eligible adult ESRD beneficiaries. This illustrates that Medicare Part D spending for the same category of drugs is more expensive for ESRD beneficiaries with Medicare Part D.

MedPAC has also noted the benefits of the future incorporation of phosphate binders into the ESRD PPS bundled payment as of January 1, 2025. As noted in MedPAC's report titled March 2022 Report to the Congress: Medicare Payment Policy,[21] this is expected to result in better drug therapy management for the ESRD beneficiary, and to improve their access to these medications. MedPAC stated that this is especially important since some beneficiaries lack Part D coverage, or

[18] Report to the Congress: Medicare Payment Policy, March 2017. p. 169. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar17_medpac_ch6.pdf.*

[19] Am J Kidney Dis 2018 Feb;71(2):246–253. doi: 10.1053/j.ajkd.2017.09.007. Epub 2017 Nov 28. CMS's data also confirms this figure.

[20] *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

[21] *https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/.*

have coverage less generous than the standard Part D benefit. MedPAC also noted that in addition to supporting equitable access for the ESRD beneficiaries, including phosphate binders in the ESRD PPS bundled payment might improve provider efficiency. MedPAC stated, and we have confirmed, that between 2018 and 2019, Medicare total spending increased for the phosphate binders that did not have generic competitors.

(4) The Oral-Only Drug Definition and ''Functional'' Equivalence Under the ESRD PPS

As noted previously in this section of the proposed rule, under § 413.234(a), we define an oral-only drug as ''A drug or biological product with no injectable equivalent or other form of administration other than an oral form.'' In addition, § 413.234(d) provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration. We note that there are various types of drug equivalences that are defined in regulation by FDA, including pharmaceutical equivalents, bioequivalents, and therapeutic equivalents.[22] However, we have not relied on these types of drug equivalences defined by FDA for purposes of the oral-only drug policy under the ESRD PPS.

Moreover, our regulations do not currently specify the meaning of the term ''equivalent'' in the definition of ''oral-only drug''.[23] We believe that the history of the ESRD PPS and our longstanding drug designation process indicate that CMS must consider ''functional'' equivalence, which is not described in FDA's regulations, in order to evaluate whether there is another form of administration other than an oral form and determine if a drug or biological product is an oral-only drug. For the purpose of ESRD PPS, we consider a drug or biological product to be functionally equivalent if it has the same end action effect as another renal dialysis drug or biological product. For example, when we first developed the Medicare ESRD PPS, we examined all renal dialysis drugs and biological products included in the prior composite rate payment system. Functional substitutes for those drugs or biological products were part of that evaluation. In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained our process for identifying drugs and biological products used for the treatment of ESRD 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 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 codified our longstanding drug designation process at § 413.234 and reiterated that injectable and intravenous drugs and biological products were grouped 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. We further clarified that the ESRD PPS functional categories are not based on their mode of action, but rather end action effect (80 FR 69015 through 69017). Accordingly, and as noted previously in this section of this proposed rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69017 and 84 FR 60803).

Our guidance has also indicated that we consider functional equivalence when assessing whether particular drugs are renal dialysis services paid for under the ESRD PPS. The Medicare Benefit Policy Manual, Chapter 11, Section 20.3F states, ''Drugs that were used as a substitute for any of these drugs [that is, drugs that were considered composite rate drugs and not billed separately prior to the implementation of the ESRD PPS] or are used to accomplish the same effect are also covered under the composite rate.'' Given that we rely on functional equivalence in determining whether drugs are reflected in an ESRD PPS functional category and thus are renal dialysis services paid for under the ESRD PPS, we believe the same standard should apply when determining if a drug is an oral-only drug.

(5) Proposed Revision to the Definition of Oral-Only Drug

Based on our observations regarding renal dialysis drug utilization and spending and the upcoming changes related to payment for oral-only drugs under the ESRD PPS, we are proposing a change to the definition of oral-only drug at § 413.234(a). The current definition states that an oral-only drug is a drug or biological product with no injectable equivalent or other form of administration other than an oral form. We are proposing to modify the definition to specify that equivalence refers to functional equivalence, in line with our current drug designation process, which relies on the ESRD PPS functional categories. The proposed definition would state that an oral-only drug is a drug or biological product with no functional equivalent or other form of administration other than an oral form. We are proposing that this change would take effect beginning January 1, 2025, to coincide with the incorporation of oral-only drugs into the ESRD PPS bundled payment under § 413.174(f)(6).

We are proposing this change for several reasons. First, we note that it would be consistent with the policies previously established for phosphate binders and calcimimetics. As discussed previously in this section of the proposed rule, in the CY 2016 ESRD PPS final rule, we finalized that when a non-oral form of administration of a phosphate binder or calcimimetic is approved by FDA, we would go through rulemaking to include the oral and any non-oral form of administration of the drug in the ESRD PPS bundled payment. We explained that we would not take this approach for any subsequent drugs that are approved by FDA and fall within the bone and mineral metabolism functional category (or any other ESRD PPS functional categories). This is because the phosphate binders and calcimimetics were the only renal dialysis drugs for which we delayed payment under the ESRD PPS because we did not have utilization data (80 FR 69025). We believe that a revision to the oral-only drug definition to clarify that a drug is not an oral-only drug if it has a

[22] FDA has defined the terms ''pharmaceutical equivalents'', ''bioequivalence'', and ''therapeutic equivalents'' at 21 CFR 314.3(b). Therapeutic equivalence, as used in FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (see Section 1.21.15), applies only to drug products containing the same active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition. *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.*

[23] Neither ATRA, PAMA, nor ABLE includes a definition of ''equivalent'' for purposes of the oral-only drug determination. Additionally, CMS did not provide a definition for or elaborate on the meaning of ''equivalent'' for purposes of the oral-only drug determination in our prior rules.

functional equivalent is consistent with that policy; that is, only oral-only drugs that are calcimimetics and phosphate binders would be eligible for a potential base rate addition and we would not take this approach for any subsequent drugs that fall within any of the ESRD PPS functional categories (80 FR 69025). While Congress has delayed the incorporation of oral-only drugs into the ESRD PPS until January 1, 2025, and this delay still applies to the phosphate binders as oral-only drugs, we believe we can still take action now to ensure that our drug designation process clearly reflects the longstanding ESRD PPS functional category framework.

In addition, this proposed modification would help ensure that we do not perpetuate any further delays in payment for renal dialysis services under the ESRD PPS. As noted previously, throughout the years, a series of legislative actions delayed the inclusion of oral-only drugs into the ESRD PPS bundled payment, from 2014 to 2016, to 2024, to January 1, 2025. When we first implemented the payment system in 2011, we noted that there were certain advantages to delaying payment for oral-only drugs under the ESRD PPS and continuing to pay for them under Part D, such as giving ESRD facilities additional time to make operational changes. CMS believes that sufficient time has passed since 2011 and we have abundant data about historical patterns to incorporate all drugs and biological products that are renal dialysis services into the ESRD PPS bundled payment as soon as possible under current law.

Our proposed modification would help ensure that new drugs and biological products that become available in the future and that are reflected in the ESRD PPS functional categories, are properly paid as part of the ESRD PPS. In other words, by specifying that an oral-only drug is one with no injectable ''functional'' equivalent, we would limit the scope of any new drugs or biological products that could be considered oral-only drugs in the future, and would therefore facilitate incorporation of these renal dialysis services into ESRD PPS. Any new oral renal dialysis drugs or biological products that are reflected in existing ESRD PPS functional categories and have functional equivalents in those categories would not meet the definition of an oral-only drug and thus could be included in the ESRD PPS bundled payment without delay, even if the functional equivalents are not ''chemical equivalents'' (that is, products containing identical amounts of the identical active drug ingredient). This would support beneficiary access to renal dialysis service drugs and would meet the intent of the ESRD PPS functional category framework, which is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician (83 FR 56941).

We note that over the past decade, CMS has been monitoring and analyzing data regarding beneficiary access to Medicare Part D drugs, Medicare expenditure increases for renal dialysis drugs paid under Medicare Part D, health equity implications of varying access to Medicare Part D drugs among patients with ESRD, and ESRD facility behavior regarding drug utilization. We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage. As discussed earlier in this section of this proposed rule, this has significant health equity implications. For example, we have identified among these beneficiaries a significant uptake by the African-American/Black minority population for calcimimetics once we began paying for those drugs using the TDAPA under the ESRD PPS.

We believe the proposed modification of the oral-only drug definition would facilitate the inclusion of oral renal dialysis drugs into the ESRD PPS bundled payment, as opposed to payment under Medicare Part D, and therefore would support health equity for beneficiaries with oral-only drugs in their plan of care who lack Medicare Part D coverage, or have less generous than Medicare Part D standard benefit. From 2017 and 2021, between 10 to 20 percent of FFS beneficiaries on dialysis either had no Medicare Part D coverage or had coverage less generous than the Medicare Part D standard benefit. Timely inclusion of renal dialysis drugs and biological products into the ESRD PPS bundled payment would promote health equity for those beneficiaries who are not enrolled in Part D or who do not have access to these drugs through alternate insurance programs.

When compared with all FFS beneficiaries, FFS beneficiaries receiving dialysis are disproportionately young, male, disabled, and African-American, have low income as measured by dual status, and reside in an urban setting. We believe a clarification to help ensure that renal dialysis drugs and biological products are properly included in the ESRD PPS bundled payment would increase the likelihood of pharmaceutical compliance for this population of patients, promote health equity for patients that lack Medicare Part D coverage or have coverage less generous than the Part D standard benefit, and contribute to better clinical outcomes by leveling the playing field for all patients with ESRD. In addition, this proposal would support Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities through the Federal Government (86 FR 7009), which addresses conducting an equity assessment in federal agencies, and determining whether new policies, regulations, or guidance documents may be necessary to advance equity in agency action and programs.

In summary, we believe that a proposed modification to the definition of oral-only drug to specify ''functional'' equivalence would be consistent with the current policy for oral-only drugs and the ESRD PPS functional category framework, would help ensure that new renal dialysis drugs and biological products are paid for under the ESRD PPS without delay, and would continue to support health care practitioners' decision-making to meet the clinical needs of their patients. Additionally, the proposed modification would promote health equity and support proper financial incentives for ESRD facilities, in keeping with our fiduciary responsibility to the Medicare Trust Funds. For all of these reasons, we are proposing to include the word ''functional'' in the definition of oral-only drug at § 413.234(a), so that the definition would be ''a drug or biological product with no injectable functional equivalent or other form of administration other than an oral form.'' We propose that this change would be effective January 1, 2025. We seek comments on this proposal.

(6) Proposed Revisions To Clarify the ESRD PPS Functional Category Descriptions

In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), we discussed the extensive analysis of Medicare payments that we performed 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 section 1881(b)(14)(B) of the Act and 42 CFR 413.171) that would be included in the ESRD PPS base rate. We analyzed Medicare 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 also explained that categorizing drugs and biological products on the basis of drug action would allow 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).

Using this approach, we established categories of drugs and biological products that are not considered for the treatment of ESRD, categories of drugs and biological products that are always considered for the treatment of ESRD, and categories of drugs and biological products that *may* be used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49049 through 49051). Those drugs and biological products that were identified as not used for the treatment of ESRD were not considered renal dialysis services and were not included in computing the ESRD PPS base rate. The categories of drugs and biologicals that were always considered used for the treatment of ESRD were identified as access management, anemia management, anti-infectives (specifically vancomycin and daptomycin used to treat access site infections), bone and mineral metabolism, and cellular management (75 FR 49050). In the CY 2015 ESRD PPS final rule, we removed anti-infectives from the list of categories of drugs and biological products that are included in the ESRD PPS base rate and not separately payable (79 FR 66149 through 66150). The categories of drugs that were considered always used for the treatment of ESRD have otherwise remained unchanged since we finalized them in the CY 2011 ESRD PPS final rule. The current categories of drugs that are included in the ESRD PPS base rate and that may be used for the treatment of ESRD but are also commonly used to treat other conditions are antiemetics, anti-infectives, antipruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and pain management (analgesics) (79 FR 66150).

Although commenters requested that we list the specific ESRD-only drugs in the CY 2011 ESRD PPS final rule rather than specifying drugs and biological products used for the treatment of ESRD, we chose to identify drugs and biological products by functional category. We did not finalize a drug-specific list because we did not want to inadvertently exclude drugs that may be substitutes for drugs identified. We stated that using categories of drugs allows CMS to update the bundled ESRD PPS base rate accordingly as new drugs and biological products become available (75 FR 49050). Because there are many drugs and biological products that have multiple uses, and because new drugs and biological products are being developed, we stated that we did not believe that a drug-specific list would be beneficial (75 FR 49050).

However, we provided a list of the specific Part B drugs and biological products (75 FR 49205 through 49209) and the former Part D drugs that were included in the bundled ESRD PPS base rate (75 FR 49210). We emphasized that drugs or biological products furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered a renal dialysis service under the ESRD PPS and will not be eligible for separate payment. In addition, we noted that any drug or biological product used as a substitute for a drug or biological product that was included in the bundled ESRD PPS base rate would also be a renal dialysis service and would not be eligible for separate payment (75 FR 49050).

In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized the drug designation process in our regulations at § 413.234 as being dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the ESRD PPS in 2011. We discussed the history of the ESRD PPS functional category approach and noted that we grouped the injectable and intravenous drugs and biological products into ESRD PPS functional categories for the purpose of adding new drugs or biological products with the same functions to the bundled ESRD PPS base rate as expeditiously as possible. We also stated that in previous regulations we referred to these categories as drug categories, however, we believe the term functional categories is more precise and better reflects how we have used the categories. We explained that CMS has designated several new drugs and biological products as renal dialysis services because they fit within the ESRD PPS functional categories, consistent with the process noted in CY 2011 ESRD PPS final rule.

As described more fully in the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CMS established a TDAPA policy in our regulation at § 413.234 that is based on a determination as to whether or not a drug fits into an existing ESRD PPS functional category. We defined an ESRD PPS functional category in our regulation at § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

In addition, in the CY 2016 ESRD PPS final rule (80 FR 69017), we explained that commenters suggested changes to our descriptions of some of the ESRD PPS functional categories in the preamble of the CY 2016 ESRD PPS proposed rule to more precisely define the drugs that would fit into the categories. In particular, the commenters suggested changes to the anti-infective, pain management, and anxiolytic ESRD PPS functional categories to better describe how each of the categories relate to the treatment of ESRD in accordance with the statute. The commenters suggested that we remove language from the description of the antiemetic functional category to eliminate drugs used to treat nausea caused by the use of oral-only drugs because these drugs are paid outside the ESRD PPS bundled payment and are covered under a separate benefit category.

In response to these suggestions, in the CY 2016 ESRD PPS final rule, we moved the anti-infective functional group from the list of drugs always used for the treatment of ESRD to the list of drugs that may be used for the treatment of ESRD (80 FR 69017). We also adopted the commenters' recommendations regarding narrowing the functional categories to describe how the category relates to the treatment of ESRD. We explained that many of the commenters' recommendations were consistent with how we believe the categories should be defined and help to ensure that the drugs that fall into them are those that are essential for the delivery of maintenance dialysis. We presented the final ESRD PPS functional categories, as revised with suggestions from commenters, in Table 8B in the CY 2016 ESRD PPS final rule (80 FR 69018). In that CY 2016 ESRD PPS final rule table, we listed each ESRD PPS functional category and rationale for association, meaning the reason we included drugs in each category, with examples of drugs in certain categories. Table 8B also separated the functional categories into those that describe drugs always considered used for the treatment of ESRD and those that described drugs that may be used for treatment of ESRD.

In the CY 2019 ESRD PPS final rule (83 FR 56928) we discussed the current ESRD PPS functional categories as part of our final policy to expand the TDAPA to all new renal dialysis drugs and biological products without modifying the base rate for drugs in existing functional categories. We emphasized that the functional categories are deliberately broad in nature because, when a new drug becomes available, it is added to the therapeutic

armamentarium of the treating physician (83 FR 56941).

In 2021, a new antipruritic drug was granted marketing authorization by FDA. The new antipruritic drug was approved for a single indication, chronic kidney disease associated pruritus. The new antipruritic drug was approved for the ESRD PPS TDAPA in December 2021 and will receive the TDAPA from April 1, 2022 until March 31, 2024. The Change Request (CR) 12583 that established the TDAPA for Korsuva® (difelikefalin) was issued on March 15, 2022.[24] As stated in that CR, the drug qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional category, specifically, the antipruritic category. Because the new drug already fits within the antipruritic ESRD PPS functional category, the drug will receive the TDAPA for 2 years (§ 413.234(b)). After the TDAPA period, the drug will be considered included in the ESRD PPS bundled payment and there will be no modification to the base rate (§ 413.234(c)(1)(i)).

In this proposed rule, we are taking the opportunity to review the descriptions for the existing ESRD PPS functional categories and propose certain clarifications to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. These proposed revisions to the descriptions would be consistent with our current policies for the ESRD PPS functional categories and would not be changes to the categories themselves. As required by the definition in § 413.234(a), the drugs and biological products in the ESRD PPS functional categories are grouped by end action effect, and as we have stated in the past, the functional categories are deliberately broad by design to provide practitioners an array of drugs to use that meet the specific needs of the ESRD patient (83 FR 56941). In offering category descriptions, which we have also identified as rationales for association (80 FR 69015, 69016, and 69018), it has not been our intention to strictly define or limit drugs in any functional category but rather to broadly describe the renal dialysis drugs and biological products that are currently available and fall into the categories. We are proposing to make the following clarifications:

- Indicate that certain ESRD PPS functional categories may include, but are not limited to, drugs that have multiple clinical indications. For example, drugs and biological products in the anxiolytic functional category could have multiple clinical indications, and we are proposing to amend the description to reflect this understanding.
- Add the term ''biological products'' to the descriptions of several ESRD PPS functional categories, which currently refer only to ''drugs''.
- Update the examples provided in some category descriptions to describe the end-action effect of drugs or biological products included in that functional category.

These proposed clarifications to the descriptions of the ESRD PPS functional categories are shown in italics in Table 13 of this proposed rule.

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[24] *https://www.cms.gov/files/document/r11295CP.pdf.*

TABLE 13: Proposed Clarifications to ESRD PPS Functional Category Descriptions

Functional Category	*Description and Examples*
Access Management	Drugs/*biological products* used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs/*biological products* used to stimulate red blood cell production and/or treat or prevent anemia. *Examples of drugs/biological products in this category include ESAs and iron.*
Bone and Mineral Metabolism	Drugs/*biological products* used to prevent/treat bone disease secondary to dialysis. *Examples of drugs/biological products in t*his category include phosphate binders and calcimimetics.
Cellular Management	Drugs/*biological products* used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	*Drugs/biological products* used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	*Drugs/biological products u*sed to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/*biological products* in this *category are included for their action to* treat itching *secondary* to dialysis *but may have* multiple clinical indications.
Anxiolytic	Drugs/*biological products* in this *category* are included for the treatment of restless leg syndrome *secondary* to dialysis *but may* have multiple *clinical indications.*
Excess Fluid Management	Drugs/*biological products/*fluids used to treat fluid excess *or fluid* overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/*biological products/*fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs/*biological products* used to treat graft site pain and to treat pain medication overdose.

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C. Proposed Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2023 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) 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 add-on 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 TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, 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 granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, 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 CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System

(IPPS) regulations at § 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 we will use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances 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; an improved quality of life; or (6) 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 or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

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

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

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility 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. We 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. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. We stated that the TPNIES is paid for two calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In

addition, a copy of the applicable 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. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (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). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that 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 are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, 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 considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID–19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule 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 § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In accordance with § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular CY, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular CY. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.[25] We finalized that this amount will be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect 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 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.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a 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 within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete 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 DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

We received three applications for the TPNIES for CY 2023. A discussion of these applications is presented below.

a. CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System)

CloudCath submitted an application for the TPNIES for the CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) for CY 2023. According to the applicant, the CloudCath System is a tabletop passive drainage system that detects and monitors solid particles in dialysate effluent during peritoneal dialysis (PD)[26] treatments. Solid particles in dialysate effluent, manifesting itself as cloudy dialysate, may indicate that the patient has peritonitis, an inflammation of the peritoneum in the abdominal wall, usually due to a bacterial or fungal infection.[27] PD therapy is a common cause of peritonitis.[28] If left untreated, the condition can be life threatening.[29] We note that CloudCath previously submitted an application for the TPNIES for the CloudCath System for CY 2022, as summarized in the CY 2022 ESRD PPS proposed rule (86 FR 36343 through 36347), but withdrew that application prior to the issuance of the CY 2022 ESRD PPS final rule (86 FR 61889). As indicated in the CY 2022 ESRD PPS final rule (86 FR 61889), the applicant withdrew its application from consideration after the issuance of the CY 2022 ESRD PPS proposed rule

[25] The CY 2021 TPNIES offset amount was $9.32. The CY 2022 TPNIES offset amount is $9.50. CMS is proposing a CY 2023 TPNIES offset amount of $9.73, as discussed in section II.B.1.(e) of this proposed rule.

[26] Peritoneal Dialysis: Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[27] Mayo Clinic Staff, ''Peritonitis,'' June 18, 2020, available at: *https://www.mayoclinic.org/diseases-conditions/peritonitis/symptoms-causes/syc-20376247*.

[28] *Ibid.*

[29] *Ibid.*

because it did not receive FDA marketing authorization by July 6, 2021, which was the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services. Under § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by that deadline prior to the particular calendar year. Therefore, as we stated in the CY 2022 ESRD PPS final rule, the CloudCath System was not eligible for consideration for the TPNIES for CY 2022.

PD-related peritonitis is a major complication and challenge to the long-term success and adherence of patients on PD therapy.[30] The applicant stated that only about 12 percent of eligible patients are on PD therapy.[31] The applicant claimed that the risk of PD-related peritonitis, and the challenges to detect it, are the main reasons for these figures. The guidelines for diagnosis of PD-related peritonitis, as outlined by the International Society for Peritoneal Dialysis (ISPD), recommend that peritonitis be diagnosed when at least two of the following criteria are present: (1) the patient experiences clinical features consistent with peritonitis (abdominal pain and/or cloudy dialysate effluent); (2) the patient's dialysate effluent has a whole blood count (WBC) >100 cells/μL or >0.1 × 10/L with polymorphonuclear (PMN) cells >50 percent; and (3) positive dialysis effluent culture is identified.[32] Additionally, the guidelines recommend that PD patients presenting with cloudy effluent be presumed to have peritonitis and treated as such until the diagnosis can be confirmed or excluded.[33] Per the guidelines, this means that for patients undergoing PD treatments at home, it is recommended that they self-monitor for symptoms of peritonitis, cloudy dialysate and/or abdominal pain, and seek medical attention for additional testing and treatment upon experiencing any or both of these symptoms.

According to the applicant, despite the fact that peritonitis is highly prevalent, symptom monitoring is insensitive and non-specific, which can contribute to late presentation for medical attention and treatment. The applicant asserted that under the current standard of care, PD patients face the following challenges in detecting peritonitis. First, the applicant stated that patients' fluid observation has low compliance rates as it relies on patients' close examination of their own dialysate effluent during PD treatments, which often occur while patients are asleep. Second, the applicant noted that it can be difficult for patients to visually detect peritonitis in dialysate effluent using a ''newspaper test'' for cloudiness, and can be even more difficult to see when the fluid is drained into a toilet, where it is diluted by water. The applicant stated that, as a result of these challenges, patients with ESRD suffer unsatisfactorily high mortality and morbidity from peritonitis, as well as high rates of PD modality loss, meaning they must discontinue PD and begin a different type of dialysis treatment. Per the applicant, the CloudCath System addresses these challenges by detecting changes in dialysate effluent at much lower levels of particle concentrations than the amount needed to accumulate for visual detection by patients.

Per the applicant, the CloudCath System consists of three components: (1) drain set, (2) sensor, and (3) patient monitoring software. As explained in the application, the CloudCath System's drain set connects to a compatible PD cycler's drain line to enable draining and monitoring of dialysate effluent before routing the fluid to the drainage receptacle. Per the CloudCath System User Guide, included in the application, the CloudCath System is compatible with the following PD cyclers: Baxter Healthcare Home Choice PRO™, Baxter Healthcare AMIA™ Automated PD System, and Fresenius Liberty® Select Cycler. Per the applicant, once the CloudCath System is attached to a compatible cycler, the dialysate effluent runs through the drain set, through the CloudCath System's optical sensor. The applicant explained that the CloudCath System's optical sensor detects and monitors changing concentrations of solid particles in the dialysate effluent during each dialysis cycle and reports the concentrations in a turbidity score. Per the applicant, the CloudCath System will indicate whether dialysate effluent has normal turbidity and will notify the patient and/or health care professional if the dialysate effluent turbidity has exceeded the notification threshold set by the patient's dialysis provider. The applicant stated that the optical sensor's hardware and software components allow for data trending over time and remote monitoring by a health care professional.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, monitoring for peritonitis is a service furnished to individuals for the treatment of ESRD that is essential for the delivery of maintenance dialysis, and therefore the CloudCath System would be considered a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the CloudCath System received FDA marketing authorization on February 9, 2022. Therefore, the CloudCath System is considered new.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the CloudCath System is not currently commercially available but noted that it expects the CloudCath System will be commercially available immediately after receiving FDA marketing authorization. We do not have information as to whether the product became currently commercially available following the FDA marketing authorization on February 9, 2022. We seek comment on the CloudCath System's commercial availability.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 5, 2022, the applicant stated that it has not submitted an application yet, but intends to apply by the deadline.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is

[30] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[31] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[32] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[33] *Ibid.*

innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant made two claims. First, the applicant asserted that the CloudCath System offers substantial clinical improvement over technologies currently available for the Medicare patient population by offering the ability to monitor changes in turbidity of peritoneal dialysate effluent through continuous remote monitoring in patients with ESRD receiving PD therapy earlier than the current standard of care. Per the applicant, by allowing the clinical standard of care to be initiated earlier, the use of the CloudCath System changes the management of peritonitis patients by enabling clinicians to both diagnose peritonitis and initiate antibiotic treatment earlier. Second, the applicant asserted that the CloudCath System offers substantial clinical improvement over existing technologies because the device's remote monitoring capabilities provides patients with oversight and increased confidence that should peritonitis occur, it will be detected more reliably than visual detection and earlier than the current standard of care, allowing for earlier diagnosis and treatment management. The applicant claimed that by alleviating the fear associated with peritonitis and providing this additional support and confidence to patients, the CloudCath System can enable patients to either switch to or remain on home–PD, ultimately improving quality of life.

The applicant submitted two studies on the technology in support of its substantial clinical improvement claims. First, the applicant included a preliminary, unpublished report by Briggs, et al. of a proof of principle observational study that tested the ability of the CloudCath System and its dialysate effluent monitoring algorithm to detect indicators of peritonitis.[34] The study consisted of 70 PD patients outside of the U.S. who had been on PD for a long interval of time (>10 days), and thus were at an increased risk of developing peritonitis. Out of the 64 PD patients whose data were included in the study, over 40 PD patients were receiving intermittent PD,[35] which is not commonly used in the U.S. The remainder of the study participants were receiving Continuous Ambulatory Peritoneal Dialysis (CAPD).[36] The report states that in the U.S., PD is generally performed in a modality called Continuous Cycling Peritoneal Dialysis (CCPD),[37] in which a cycler automatically administers multiple dialysis exchange cycles, typically while patients sleep. Samples were collected from patients' PD effluent drainage bags and measured in the CloudCath System against a proprietary Turbidity Score threshold value and also tested for reference laboratory measurements according to ISPD guidelines for WBC count and differential (>100 cells/μL, >50 percent PMN).[38] Regarding the Turbidity Score threshold value, the study set a score to determine if the effluent sample in the CloudCath System was infected or not; samples greater than or equal to the Turbidity Score threshold value would be classified as infected, and samples less than the Turbidity Score threshold value would be classified as non-infected. The crude sensitivity and specificity of the CloudCath System was 96.2 percent and 91.2 percent, respectively. A majority of false positives (44 of 77 samples) occurred among patients already receiving antibiotic treatment for peritonitis, and another 20 false positive reports occurred because the patient had elevated turbidity due to a cause other than peritonitis. The investigators subsequently removed samples from patients already receiving treatment for peritonitis, setting the sensitivity for detecting peritonitis using the CloudCath System at 99 percent and the specificity at 97.6 percent.

The second study the applicant submitted is the Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH).[39] The applicant stated that it initiated this ongoing single-arm, open-label, multi-center study to demonstrate that the CloudCath System is able to detect changes in turbidity associated with peritonitis in PD patients prior to laboratory diagnosis of peritonitis with a high degree of specificity and sensitivity. The target enrollment is 186 participants over 18 years of age using CCPD as their PD modality, with at least 2 exchanges per night.[40] Patients with active infection and/or cancer are excluded from the trial.[41] The primary endpoint is time of peritonitis detection by the CloudCath System (defined as two consecutive Turbidity Scores >7.0) as compared to laboratory evidence of peritonitis (defined as WBC count >100 cells/μL or >0.1 × 109/L with percentage of PMN >50 percent).[42] While the study is ongoing, the applicant included the study protocol and the first preliminary results with its application.[43] According to the applicant, the first preliminary results demonstrate that as of December 29, 2020, 132 participants were enrolled in the CATCH Study at 13 sites.[44]

Enrolled participants underwent an average of 4.5 dialysate exchanges per night.[45] The preliminary results indicated that, as of December 29, 2020, there have been 7 peritonitis events that met the ISPD peritoneal fluid cell counts and differentials standard.[46] According to the applicant, 5 of the 7 peritonitis events described in the CATCH study occurred after initial use

[34] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[35] Intermittent Peritoneal Dialysis (IPD)—Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[36] Continuous Ambulatory Peritoneal Dialysis (CAPD)—In CAPD, the patient's peritoneal membrane is used as a dialyzer. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted indwelling catheter that allows the dialysate to pour into the beneficiary's peritoneal cavity. Every 4 to 6 hours the patient drains the fluid out into the same bag and replaces the empty bag with a new bag of fresh dialysate. This is done several times a day. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[37] Continuous Cycling Peritoneal Dialysis (CCPD)—CCPD is a treatment modality that combines the advantages of the long dwell, continuous steady-state dialysis of CAPD, with the advantages of automation inherent in intermittent peritoneal dialysis. The solution exchanges, are performed at nighttime and are performed automatically with a peritoneal dialysis cycler. Generally, there are three nocturnal exchanges occurring at intervals of 2½ to 3 hours. Upon awakening, the patient disconnects from the cycler and leaves the last 2-liter fill inside the peritoneum to continue the daytime long dwell dialysis. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[38] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[39] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[40] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Study Protocol (CC–P–001), June 24, 2020.

[41] *Ibid.*

[42] *Ibid.*

[43] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[44] *Ibid.*

[45] *Ibid.*

[46] *Ibid.*

of the CloudCath System, and all 5 of the peritonitis events were also detected by the CloudCath System.[47] In the 5 events, the CloudCath System detected peritonitis 44 to 368 hours prior to the time of detection from a clinical laboratory.[48] The CloudCath System also detected peritonitis 27 to 344 hours prior to participants presenting to the hospital or clinic with signs or symptoms of peritonitis.[49] The applicant stated that these results support the claim that the CloudCath System would enable diagnosis of peritonitis earlier than the current standard of care through turbidity monitoring. According to the applicant, in the remaining 2 peritonitis events, participants experienced peritonitis prior to initial use of the CloudCath System, however, the CloudCath System detected peritonitis upon initial use.

In addition to the studies on the technology, the applicant submitted an article by Muthucumarana, et. al. on the impact of time-to-treatment on clinical outcomes of PD-related peritonitis.[50] The article included data from the Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis (PROMPT) Study, a prospective multicenter study from 2012 to 2014 that observed symptom-to-contact time, contact-to-treatment time, defined as the time from health care presentation to initial antibiotic, and symptom-to-treatment time in Australian PD patients. One hundred sixteen patients participated in the survey.[51] Out of the sample size of 116 survey participants, there were 159 episodes of PD-related peritonitis. Of these, 38 patient episodes met the primary outcome of PD failure (defined as catheter removal or death) at 30 days.[52] The median symptom-to-treatment time was 9.0 hours in all patients, 13.6 hours in the PD-fail group, and 8.0 hours in the PD-cure group.[53] The study found that the risk of PD-failure increased by 5.5 percent for each hour of delay of administration of antibiotics once patients presented to a health care provider.[54] However, neither symptom-to-contact nor symptom-to-treatment was associated with PD-failure in non-adjusted analyses, and the time from presentation to a health care provider to treatment was only associated with PD-failure outcomes in multivariable-adjusted analyses in a subset of patients who presented to hospital-based facilities. In addition to the Muthucumarana et. al. article, the applicant cited to other studies that have found that antibiotic treatment should begin as soon as possible in order to effectively treat infections other than peritonitis. [55] [56] [57] Per the applicant, these articles on time-to-treatment demonstrate that the CloudCath System's ability to detect effluent changes substantially earlier improves the standard of care, enabling PD-related peritonitis diagnosis and antibiotic treatment earlier while decreasing the likelihood of PD-failure due to PD-related peritonitis.

The applicant also submitted letters of support from a nephrologist at an academic institution and the following ESRD patient advocacy groups: the American Kidney Fund, the American Association of Kidney Patients, and the International Society of Nephrology. The nephrologist's letter of support endorsed the CloudCath System's ability to detect peritonitis and enable clinicians to begin to treat the infection earlier, preventing hospitalizations and complications such as the abandonment of home dialysis. The nephrologist's letter also asserted that the CloudCath System helps address the challenge of peritonitis as the main reason for abandonment of PD for HD, and will encourage a greater number of patients to select PD as their dialysis modality of choice. The letters from the American Association of Kidney Patients and the International Society of Nephrology encouraged CMS to consider the CloudCath System's TPNIES application, explaining that the technology would have several benefits to patients, for example, by reducing peritonitis-related hospitalizations, increasing adherence to PD, and encouraging higher utilization of PD as a viable alternative to in-center HD. The American Kidney Fund's letter emphasized that peritonitis is a significant concern for PD patients [58] and requested CMS support of all efforts that ensure patients with ESRD undergoing PD treatments can quickly detect and treat infections.

As noted previously in this section of the proposed rule, the applicant previously submitted a TPNIES application for CY 2022, but withdrew its application. Compared to the CY 2022 application, the applicant updated the number of patients and sites that were enrolled in the CATCH study. In its CY 2022 application, the applicant reported that as of December 29, 2020, 132 patients were enrolled in the CATCH study at 15 sites. In its CY 2023 application, the applicant provided updated enrollment figures and stated that as of May 5, 2021, 185 patients were enrolled in the CATCH study at 15 sites.

In response to CMS' preliminary assessment of CloudCath's substantial clinical improvement claims in the CY 2022 ESRD PPS proposed rule, the applicant provided additional information to clarify how the CloudCath System fits into the current standard of care and how use of the CloudCath System affects the management of the patient. The applicant stated that the monitoring of changes in turbidity enabled by the CloudCath System does not require clinicians to deviate from their current diagnosis or treatment sequence, since sign and symptom monitoring is an already accepted trigger for subsequent clinical steps and patient management. However, per the applicant, the detection of turbidity does allow clinicians to evaluate patients earlier in this clinical pathway for diagnosis of peritonitis and antibiotic/antimicrobial treatment in accordance with the ISPD guidelines. The applicant further stated that earlier detection of turbidity would not impact appropriate diagnosis and treatment with respect to false positives and that, while a small number of patients in the Briggs et al. study showed a change in turbidity that ultimately resulted in a false positive for infection, these patients would not have received inappropriate use of antimicrobial therapy compared to the standard of care per ISPD guidelines. The applicant further stated that even though the CloudCath System may in some instances detect change in turbidity in patients without infection,

[47] *Ibid.*

[48] *Ibid.*

[49] *Ibid.*

[50] Muthucumarana, et al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[51] *Ibid.*

[52] *Ibid.*

[53] *Ibid.*

[54] *Ibid.*

[55] Gacouin, A. et al., ''Severe pneumonia due to Legionella pneumophila: prognostic factors, impact of delayed appropriate antimicrobial therapy,'' Intensive Care Medicine 28, 686–691 (2002), *https://doi.org/10.1007/s00134-002-1304-8.*

[56] Houck, PM. et al., ''Timing of antibiotic administration and outcomes for Medicare patients hospitalized with community-acquired pneumonia,'' Arch Intern Med. 2004 Mar 22;164(6):637–44. doi: 10.1001/archinte.164.6.637. PMID: 15037492.

[57] Lodise TP, et al., ''Outcomes analysis of delayed antibiotic treatment for hospital-acquired Staphylococcus aureus bacteremia,'' Clin Infect Dis. 2003 Jun 1;36(11):1418–23. doi: 10.1086/375057. Epub 2003 May 20. PMID: 12766837.

[58] Mehrotra, Rajnish et al., ''The Current State of Peritoneal Dialysis,'' Journal of the American Society of Nephrology 27: 3238–3252, 2016. doi: 10.1681/ASN.2016010112, available at: *https://jasn.asnjournals.org/content/jnephrol/27/11/3238.full.pdf?with-ds=yes.*

these patients would still be clinically evaluated for peritonitis diagnosis and eligibility for antimicrobial treatment by a clinician as per the existing standard of care with the change in turbidity. Therefore, the applicant asserted, the CloudCath System does not result in increased provision of unnecessary antimicrobial therapy, nor deviate from the ISPD guidelines in terms of antimicrobial treatment pattern.

(b) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant regarding the CloudCath System, we note the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1). We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether the CloudCath System meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

Because the applicant claims to offer the ability to diagnose a medical condition, PD-related peritonitis, earlier in a patient population than allowed by currently available methods, the applicant must also include evidence that use of the new technology to make a diagnosis affects the management of the patient, as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B). Specifically, § 412.87(b)(1)(ii)(B) states that a determination that a technology represents substantial clinical improvement over existing technology means: the new medical service or technology 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 medical service or technology to make a diagnosis affects the management of the patient.

As we noted previously in the CY 2022 ESRD PPS proposed rule (86 FR 36346 through 36347), it is not clear to us whether the studies submitted demonstrate or examine the impacts of using the technology on patients with ESRD such that we can determine whether it represents an advance that substantially improves the treatment of Medicare beneficiaries compared to renal dialysis services previously available. We note that the studies submitted serve as ''proof of concept,'' as they are testing whether the CloudCath System detects turbidity in dialysate effluent that may indicate PD-related peritonitis, and whether they do so earlier than patient observation and a cell count test. However, the studies are limited in that they do not observe how the CloudCath System, in measuring the turbidity in dialysate effluent and doing so earlier than traditional self-monitoring, affects the management of the patient as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B). For example, as part of the CATCH Study, investigators deactivated the notification capability of the CloudCath System for the duration of the study, so that neither the participants nor the investigators would be aware of the device measurements.[59] Therefore, as currently designed, the CATCH study may not examine patient and clinician behavior, including the medical management of the patient, after the CloudCath System detected the solid particles in the dialysate effluent. The Briggs et al. study also did not examine how use of the CloudCath System impacted management of the patient. The investigators in that study stated that none of the data from the device was used for clinical decision making, which indicates to us that the study did not test how or if the CloudCath System offered the ability to diagnose a medical condition and how use of the CloudCath System to make a diagnosis affected the management of the patient.[60] Because the studies submitted did not observe how patients and clinicians use the CloudCath System's monitoring to make decisions regarding patient management, it is unclear how they support a finding that early detection of PD-related peritonitis by the CloudCath System meets the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B).

Similarly, while the applicant submitted evidence to show that time-to-treatment plays a role in preventing PD failure in patients with ESRD with PD-related peritonitis,[61] CMS has not received information regarding how the CloudCath System would affect management of the patient by reducing time-to-treatment for patients with ESRD receiving PD therapy. CMS also notes that the applicant referenced studies that support beginning antibacterial therapy for infections other than PD-related peritonitis, like pneumonia, and therefore, do not directly demonstrate the importance of time-to-treatment for PD-related peritonitis.

As we noted in the CY 2022 ESRD PPS proposed rule, it is also not clear to us whether the CloudCath System would affect medical management of the patient because use of the technology may potentially detect turbidity changes in dialysate effluent so early, that, in some cases, health care providers may still decide to wait for confirmation via patient symptoms, cell count, or positive culture as stated in the ISPD guidelines on diagnosis.[62] It is unclear whether clinicians would begin treatment for peritonitis without observing patient symptoms, cloudy dialysate, or confirming cell count via fluid test or how turbidity information would be incorporated into clinical practice among physicians who may empirically treat asymptomatic patients with antibiotics while awaiting cell count and culture results to confirm a peritonitis diagnosis.

We note that the applicant stated that the first preliminary results of the CATCH study demonstrated that the CloudCath System detected PD-related peritonitis 33 to 367 hours prior to the time of detection from a clinical laboratory, and it also detected PD-related peritonitis 27 to 344 hours prior to participants presenting to a healthcare facility with symptoms of PD-related peritonitis. [63] [64] However, we note that no evidence was submitted to show that clinicians would begin to treat suspected peritonitis if the CloudCath System alerted the patient and clinician of possible PD-related peritonitis that was too early to detect via any of the ISPD guidelines.[65] In

[59] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report, NCT04515498, Jan 27, 2020.

[60] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[61] Muthucumarana, et. al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[62] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[63] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[64] *Ibid.*

[65] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and

Continued

other words, we have not received evidence to demonstrate that the CloudCath System would affect medical management of the patient by replacing one of the ISPD guidelines for diagnosis.[66] As two criteria are necessary for diagnosis of peritonitis (per ISPD guidelines noted by the applicant), it is unclear why the CloudCath System detection alone in the control arm (absent clinical manifestations such as symptomatic patients or cloudy effluent) is comparable as a diagnosis of peritonitis to patients with clinical manifestations plus laboratory evidence of peritonitis. In other words, we question whether a more appropriate comparison to demonstrate a time difference would be time to laboratory-confirmed peritonitis in both study arms, or time to antibiotic initiation following the CloudCath System notification versus antibiotic initiation following standard of care patient monitoring.

Further, we are concerned by the applicant's statements in response to the concerns we noted in the CY 2022 ESRD PPS proposed rule that the monitoring of changes in turbidity enabled by the CloudCath System does not require clinicians to deviate from their current diagnosis or treatment sequence. As stated previously, our regulations under § 412.87(b)(1)(ii)(B) require evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient. Therefore, we request information that demonstrates that the CloudCath System affects the management of the patient, including by impacting clinicians' diagnosis or treatment sequence.

While the applicant updated the CY 2023 application to include more patient and site enrollment, CMS has concerns that the CATCH trial is not designed to indicate potential changes in clinical practice in a way that would be helpful for substantial clinical improvement assessment. We welcome additional information regarding whether use of CloudCath has demonstrated lower hospitalization rates, an increase in PD use, or decrease in peritoneal dialysis modality loss, or improved mortality for our analysis. We also believe that any data on clinician and patient behavior while using the CloudCath System, for example by enabling CloudCath notifications or alarms in the CATCH Study, would be informative in our assessment.

Finally, regarding the applicant's claim that the CloudCath System's remote monitoring capabilities help to assure patients that peritonitis could be detected and treated earlier, and that by alleviating the fear of peritonitis, the CloudCath System enables patients to either switch to or remain on home-PD, ultimately improving quality of life, we are concerned there may be insufficient evidence to demonstrate that the CloudCath System improves patients' quality of life. The applicant referenced literature regarding health-related quality of life in home dialysis patients as well as information regarding the challenges of managing PD patients remotely. [67] [68] [69] However, we did not receive any data demonstrating improved quality of life or PD retention with the use of the CloudCath System, and we would be interested in additional evidence to support this claim.

We are inviting public comments on whether the CloudCath System meets the substantial clinical improvement criteria for the TPNIES.

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant stated that the CloudCath System is not a capital-related asset. We note that the CloudCath System does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation.[70]

b. SunWrap™ System

Sun Scientific, Inc. submitted an application for the TPNIES for the SunWrap™ System for CY 2023. According to the applicant, the technology is comprised of a compression sleeve with a transparent air bladder and hand pump designed to provide static pneumatic compression to the forearm and/or upper arm following dialysis needle removal from the arteriovenous (AV) fistula access. The applicant explained that following hemodialysis (HD), gauze is placed over the puncture sites as the needles are removed, and then the SunWrap™ System is placed around the arm with the transparent bladder positioned over the gauze-covered access site. Per the applicant, the SunWrap™ System is then inflated, compressing the site to stop bleeding. Per the applicant, the SunWrap™ System provides a sufficient source of pressure to compress the AV intervention puncture site and has adjustable compression at 20–30mmHg and 30–40 mmHg. The applicant also stated that the inflation portion of the wrap is composed of completely transparent film, allowing for visualization of the puncture site(s) and ensuring that the hemostasis can be monitored. The applicant stated that the SunWrap™ System is easy to apply, safe, non-invasive, requires minimal training of only one tutorial, and has been proven to meet patient satisfaction and safety requirements after multiple trials.

The applicant also submitted a SunWrap™ System brochure noting that the product is indicated for post-HD treatment needle puncture management for hemostasis of needle site and that it is contraindicated for use directly on an open wound. The applicant submitted the following listing of the SunWrap™ System's line of products: Upper Arm—Right Small, Upper Arm—Right Large, Forearm Right, Upper Arm—Left Small, Upper Arm- Left Large, Forearm Left, and MINI—Single Site.

The applicant stated that the SunWrap™ System is meant to replace the current method of compression for bleeding control, which relies on the patient or skilled caregiver manually applying pressure to the puncture site for up to 15 minutes following HD. Per the applicant, inadequate or incorrect application of compression can result in discomfort, excessive bleeding, hematoma, fistula damage, and potentially even death. The applicant stated that use of the SunWrap™ System allows for more consistent application of compression, frees up the hands of the patient or skilled caregiver, and allows for simultaneous visual management of the needle site.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, compression to the HD access site following dialysis needle removal is a

Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[66] *Ibid.*

[67] Bonenkamp AA, van Eck van der Sluijs et al. Kidney Medicine, Health-Related Quality of Life in Home Dialysis Patients Compared to In-Center Hemodialysis Patients: A Systematic Review and Meta-analysis. Vol.2(2) P139–154.

[68] 25 Ronco C, Crepaldi C, Rosner MH (eds): Remote Patient Management in Peritoneal Dialysis. Contrib Nephrol. Basel, Karger, 2019, vol 197, pp I–VI.

[69] Hansson JH, Finkelstein FO. Kidney Med. 2020 Sep 1;2(5):529–531.

[70] See also CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

service that is furnished to individuals for the treatment of ESRD and essential for the delivery of maintenance dialysis, and therefore would be considered a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant did not submit an FDA marketing authorization date but instead, indicated that the SunWrap™ System is considered FDA Class I Exempt. We note that under FDA regulatory scheme, Class I exempt status is determined by FDA, which maintains on its website the listing of devices exempt from the premarket notification (510(k)) requirements. As described on the FDA website, Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages.[71]

The applicant submitted the following information pertaining to Sun Scientific, Inc.'s registration and product classification: (1) a document labeled *Class I Exempt Documentation* and (2) listing, registration, and Firm Establishment Identifier (FEI) numbers for *SunWrap.* While the *Class I Exempt Documentation* lacked identifying product information such as the SunWrap™ System's product name(s) and date of the Class I Exempt status determination, we located supplemental information online. Sun-Scientific, Inc. is identified on the FDA website with Registration Number: 3008773774, FEI Number: 3008773774, and Owner/Operator Number: 10034866.[72] Twelve devices were identified with this Owner/Operator Number, but only the following two devices include the regulation number (880.5075) included in the application: Dressing, Compression—Aerowrap; SunWrap and Dressing, Compression—SunWrap.[73]

After a review of the information provided by the applicant, we note the following concerns with regard to the newness criterion under § 413.236(b)(2). Consistent with § 413.236(c), CMS will announce its final determination regarding whether the SunWrap™ System meets the newness criterion and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

First, the applicant included a product brochure and product selection listing of 7 SunWrap™ System products and did not clearly indicate which of the 7 products are the subject of the CY 2023 TPNIES application. In addition, it is not clear whether the listing and registration numbers provided apply to all 7 products. We request that the applicant clarify these points.

Second, while the applicant stated that the Sun Wrap™ System is considered FDA Class I Exempt, as indicated in § 413.236(b)(2), to be eligible for the TPNIES, the applicant must apply within three years of the FDA marketing authorization date. While our primary concern is the lack of FDA marketing authorization, we also note that the applicant did not clearly indicate the date of Class I Exempt status. Therefore, it is unclear whether the SunWrap™ System's Class I Exempt status is within the three-year window.

We note that manufacturers of devices that fall into a category of exempted Class I devices are not required to submit to FDA a premarket notification and obtain FDA clearance before marketing the device in the U.S. However, the manufacturer is required to register its establishment and list its device with FDA.[74] Devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, exempt devices still must comply with certain regulatory controls (known as ''general controls'') to provide a reasonable assurance of safety and effectiveness for such devices. Our intent in requiring applicants to receive FDA marketing authorization was to exclude devices that lack FDA marketing authorization. However, we welcome public comment on these issues.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the Sun Wrap™ System is currently commercially available.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 5, 2022, the applicant stated that it submitted that application on January 31, 2022.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant asserted that the use of the SunWrap™ System significantly improves clinical outcomes relative to the current standard of care, which it identified as reliance on the patient or a skilled caregiver manually applying pressure to the puncture site for up to 15 minutes following HD.

The applicant presented the following six substantial clinical improvement claims: (1) a reduction in at least one clinically significant adverse event; (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; (5) an improvement in one or more activities of daily living; and (6) an improved quality of life.

Regarding the first claim, a reduction in at least one clinically significant adverse event, the applicant stated that the SunWrap™ System potentially reduces the incidence of hematoma, fistula stenosis/thrombosis, and Fatal Vascular Access Hemorrhage (FVAH).

Regarding the second claim, a decreased rate of at least one subsequent diagnostic or therapeutic intervention,

[71] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 23, 2022.

[72] U.S. Food & Drug Administration. Establishment Registration & Device Listing. Sun-Scientific Inc. Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=124922.* Accessed on March 29, 2022.

[73] U.S. Food & Drug Administration. Establishment Registration & Device Listing. Sun-Scientific Inc. Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=&regNum=&StateName=&CountryName=&OwnerOperatorNumber=10034866&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=3008773774.* Accessed on March 29, 2022.

[74] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 23, 2022.

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the applicant stated that the SunWrap™ System potentially reduces the incidence of ER visits, estimated at $10,000 per visit, ultrasound assessment, or interventions for stenosis or thrombosis. The applicant also stated that the SunWrap™ System potentially reduces the incidence of hospital admissions that are estimated at $15,000 or more per admission. The applicant further stated that incident cases of ESRD are reaching nearly 21,000 annually, and that vascular access complications account for 16 to 25 percent of hospital admissions.[75]

Regarding the third claim, a decreased number of future hospitalizations or physician visits, the applicant stated that the SunWrap™ System reduces ER visits due to bleeding and the potential for subsequent admission, saving approximately $10,000 per visit.[76] The applicant also stated that the SunWrap™ System reduces the need for revascularization due to stenosis/thrombosis.[77]

Regarding the fourth claim, a more rapid beneficial resolution of the disease process treatment, the applicant stated that the SunWrap™ System reduces the need for nurses to be tied up with manual compression therapy, maximizing their efforts around dialysis treatment. The applicant also stated that the SunWrap™ System adds a layer of assurance as patients transfer to home therapy, as compression is not reliant on patient or caregiver ability to provide compression consistent with care that occurs in the clinics. Per the applicant, the SunWrap™ System provides consistent compression to needle sites post-dialysis with the ability to visualize sites through a transparent window potentially reducing the incidence of unrecognized bleeding.

Regarding the fifth claim, an improvement in one or more activities of daily living, the applicant stated that the SunWrap™ System could increase comfort levels of patients in the home setting and could help reduce fatigue-related compression interruption, and allow some normal activity while ensuring post-dialysis compression is provided, resulting in potential for improved patient satisfaction.

Regarding the sixth claim, improved quality of life, the applicant stated that the SunWrap™ System allows the patient to become more autonomous and that the ability to have their hands free while stopping bleeding post-HD is beneficial. The applicant also stated that the potential reduction in fistula complications could improve quality of life on a broader scale.

The applicant did not provide direct links to the supporting materials for each of the six claims, but rather referred more broadly to several sources of information as evidence of demonstrating substantial clinical improvement, including a U.S. Centers for Disease Control and Prevention fact sheet on Chronic Kidney Disease (CKD),[78] case studies on fatal hemorrhage from HD vascular access sites,[79] and a case study of managing fistula complications in the Emergency Department.[80] The applicant stated that there are 786,000 annual ESRD patients, 71 percent are on dialysis and 29 percent have kidney transplants.[81] Referring to Gage, et. al., the applicant stated that 75 percent of AV fistulae and AV grafts required one or more interventions; stenosis and thrombosis were the most common complications diagnosed and treated (41 percent and 16 percent respectively); and that potential needle-related complications accounted for 6 percent of this data set.[82] The applicant also asserted that a review of standard and early cannulation graft literature reveals that HD complications are similar across the graft types. The applicant further noted that in retrospective review articles, infection, hematoma, pseudoaneurysm, and bleeding occur at rates of up to 26 percent, 24 percent, 15 percent, and 14 percent, respectively.

The applicant also included a summary of what it described as evidence from an unpublished pilot study involving 54 patients in two vascular access laboratory sites, 23 and 31 patients from each site, respectively who required intervention on their AV fistula or graft access site.[83] The applicant provided background information stating that patients require AV fistula or graft interventions for various reasons such as maintenance angioplasty, fistulogram, or thrombectomy. Per the applicant, the physician normally uses sutures to close the puncture site and after the procedure, the patients are monitored in the recovery room for a few hours before the sutures are removed or patients revisit the clinic for suture removal. The applicant stated that this suturing technique is frequently used because it is quick, straightforward, and has been the common practice. The applicant further indicated that suture removal poses a risk of infection. The applicant stated that during the study, the SunWrap™ System was applied for wound closure in place of suturing with an inflation pressure at 20—40 mmHg and hold-time at 20 to 30 minutes for most of the patients because most patients were punctured with a large note sheath size of 6—8 F. The applicant also stated that in ESRD facilities, the needle size is relatively smaller and less inflation pressure and shorter hold-times are needed to achieve hemostasis. As such, the applicant asserted that the SunWrap™ System could be safely applied in the ESRD facility setting without extensive training.

The applicant noted two reported cases of immediate post-operative bleeding; one reported case (fistula) of thrombosis at 48 to 72 hours post-operatively; and three reported cases (two fistula and one graft) of thrombosis 30 days post-operatively. The applicant stated that there were no reported cases of post-operative bleeding, infection, and pseudoaneurysm at 48 to 72 hours.

Per the applicant, the two cases of immediate post-operative bleeding were directly due to the SunWrap™ System.

[75] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[76] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[77] Ibid.

[78] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2021. Available at: *https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf*. Accessed on March 17, 2022.

[79] Jose, M., Marshall, M., Read, G., Lioufas, N., Ling, J., Snelling, P., Polkinghorne, K. (2017). Fatal dialysis vascular access hemorrhage. Am J Kidney Dis., 70(4), 570–575. Available at: *https://www.sciencedirect.com/science/article/pii/S0272638617307497*. Accessed on March 17, 2022.

[80] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[81] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2021. Available at: *https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf*. Accessed on March 17, 2022.

[82] Gage SM, Reichert H. Determining the incidence of needle-related complications in hemodialysis access: We need a better system. J Vasc Access. 2021 Jul;22(4):521–532. doi: 10.1177/1129729820946917. Epub 2020 Aug 18. PMID: 32811335. Available at: *https://pubmed.ncbi.nlm.nih.gov/32811335/*Accessed on March 17, 2022.

[83] Summary points included in the application identified as: Sun-Wrap A Novel device for arteriovenous (AV) access hemostasis, Presented by Steven H.S. Tan, M.D. & Sundaram Ravikumar, M.D., FACS.

Per the applicant, the first case occurred during training in the initial phase of the study and there was no repetitive event after modification of the technique and timing of the application of the SunWrap™ System. We note that the applicant did not specify the way in which the technique or timing of applying the SunWrap™ System were modified. The applicant stated that the second case was due to two distant puncture sites that exceeded the coverage for the SunWrap™ System. Per the applicant, in patients with two puncture sites that measure more than 7.5 cm apart or if there is immediate bleeding, suturing is the treatment of choice.

The applicant stated that the thrombosis cases identified (one case at 48 to 72 hours post-operatively and three cases 30-days post-operatively) were not directly due to the SunWrap™ System. Per the applicant, the patients did not have any complications while on the SunWrap™ System and left the clinic safely after thorough monitoring in the recovery room. The applicant further stated that the patients underwent dialysis after the removal of the SunWrap™ System and asserted that the dialysis may have been the major contributing factor for the thrombosis.

(b) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant, we note the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1). Consistent with § 413.236(c), CMS will announce its final determination regarding whether the SunWrap™ System meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

The applicant stated that the SunWrap™ System has the potential to represent substantial clinical improvement. However, it is not clear whether or how the evidence submitted by the applicant supports the applicant's 6 substantial clinical improvement claims. It would be helpful for our evaluation if the applicant would directly link each claim to the relevant supporting information. The applicant provided summary points of a non-published, single pilot study of 54 patients treated with the SunWrap™ System at two vascular access laboratory sites. While the applicant provided a bullet-point summary of the study setting, complications, and a brief discussion of study data, the applicant did not provide details pertaining to study type, timeframe, patient demographics and endpoints. We note that this study appears to involve patients treated with the SunWrap™ System for the purpose of controlling bleeding following interventional procedures involving an AV fistula or graft and does not involve use of the SunWrap™ System following HD treatment in the ESRD facility setting. We question the extent to which this data would be generalizable to the ESRD facility setting and would be interested in any data pertaining to the use the SunWrap™ System for the purpose of controlling bleeding in the ESRD facility setting; specifically, at the needle puncture sites following HD.

We also note that the applicant stated that the SunWrap™ System provides static pneumatic compression to the forearm and/or upper arm with a gauze bandage, following dialysis needle removal from the AV fistula access. We request clarification as to whether the SunWrap™ System's indication for use is limited to patients with AV fistula access sites or if it is also indicated for use among patients with AV graft access sites.

The applicant identified 6 cases of post-operative complications within the pilot study, stating that two were directly due to the SunWrap™ System and that the 4 remaining cases were unrelated to the SunWrap™ System, but did not offer data to substantiate this statement. In addition, the applicant stated that the SunWrap™ System has met patient satisfaction and safety requirements after multiple trials, but did not provide specific information in support of this statement within the application. We would appreciate additional information regarding these trials, as well as any additional data demonstrating that the SunWrap™ System represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, it would be useful to consider data comparing the SunWrap™ System's outcomes to outcomes of patients treated by manual compression at the puncture site following HD.

The applicant referred to the SunWrap™ Mini, stating that it targets single puncture sites and may be useful for achieving hemostasis for puncture sites which are more than 7.5 cm apart, may be easier to use in ESRD facilities, and is currently in its initial phase of study. As noted previously in this section of the proposed rule, the applicant provided a listing of 7 SunWrap™ System products. We request clarification as to which of the 7 SunWrap™ System products were included in the primary pilot study of 54 patients. We welcome public comment on these issues.

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant did not address this criterion within its application. However, because the SunWrap™ System is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation, it is not a capital related asset.[84]

c. THERANOVA 400 Dialyzer/ THERANOVA 500 Dialyzer (THERANOVA)

Baxter Healthcare Corporation (Baxter) submitted an application for the TPNIES for the THERANOVA 400 Dialyzer/THERANOVA 500 Dialyzer, collectively referred to as ''THERANOVA,'' for CY 2023. According to the applicant, THERANOVA is a new class of single-use dialyzer, featuring an innovative three-layer membrane structure that enables more comprehensive removal of certain harmful proteins known as large middle molecules (LMMs), while selectively maintaining essential proteins in the blood during hemodialysis (HD), compared to conventional low-flux and high-flux dialyzers. The applicant noted that the '400' and '500' denote differences in surface area. The applicant stated that THERANOVA is used with standard HD machines, like most other high-flux dialyzers, but has unique membrane properties that allow for enhanced removal of LMM uremic toxins contributing to disease burden (cardiovascular disease, development of inflammation, and other comorbidities) while retaining appropriate levels of beneficial molecules such as albumin, coagulation factors, and immunoglobulins. We note that Baxter previously submitted an application for the TPNIES for THERANOVA for CY 2021, as discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42167 through 42177) and the CY 2021 ESRD

[84] 42 CFR 413.236(a)(2); CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

PPS final rule (85 FR 71444 through 71457).[85]

The applicant stated that THERANOVA is intended to treat kidney failure by expanded hemodialysis (HDx). The applicant noted that previous dialyzers were only able to remove toxins up to 25 kilodaltons (kDa), while HDx, enabled by the THERANOVA dialyzer, can remove molecules from 25 kDa to approximately 45 kDa. The applicant explained that patients with CKD have increasing difficulty removing these solutes as their kidneys fail. The applicant further explained that these non-protein bound uremic solutes can be divided into three main categories: (1) small molecules (SMs), <0.5 kDa, with effective removal by diffusion, (2) small and medium middle molecules (SMMMs), 0.5 − <25 kDa, with limited removal by diffusion, and (3) large middle molecules (LMMs), 25 − 60 kDa, which requires higher permeability membranes for effective and efficient removal.[86] The applicant noted that evidence to date demonstrates a strong link between LMMs and the development of different outcome-related morbidities, and that uremia related to the retention of SMMMs/LMMs is associated with inflammation and cardiovascular events.[87] [88] [89] The applicant stated that THERANOVA's innovative hollow fiber, medium cut-off (MCO) membrane shows a permeability profile close to that of the natural kidney and expands the range of uremic toxin removal beyond what is achieved with current membranes during regular HD.

The applicant asserted that the design of THERANOVA allows for use on any HD machine, both in-center and home, made by Baxter or another 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.[90]

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

With respect to the first TPNIES eligibility criterion under § 413.236(b)(1), whether the item has been designated by CMS as a renal dialysis service under § 413.171, maintenance dialysis treatments and all associated services, including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time, were included in the composite rate for renal dialysis services as of December 31, 2010 (75 FR 49036). A dialyzer would be considered a supply essential for the delivery of maintenance dialysis and, therefore, we would consider this a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion under § 413.236(b)(2), whether the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the THERANOVA received FDA marketing authorization for home use on August 28, 2020. Therefore, the THERANOVA is considered new.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

With respect to the third TPNIES eligibility criterion under § 413.236(b)(3), whether the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that THERANOVA is commercially available in the U.S.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

With respect to the fourth TPNIES eligibility criterion under § 413.236(b)(4), whether the applicant submitted a HCPCS Level II code application by the July 5, 2022 deadline, the applicant stated a HCPCS application was submitted on June 27, 2020, and it intends to resubmit a HCPCS Level II code application by the July 5, 2022 deadline.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With respect to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant asserted that THERANOVA significantly improves clinical outcomes relative to the current standard of care for dialysis membranes. The applicant presented the following substantial clinical improvement claims: (1) decrease in the number of future hospitalization by up to 45 percent; (2) improved recovery time by up to 2 hours; (3) improved quality of life (QoL) as indicated by reduced pruritus, improvement in two Kidney Disease Quality of Life (KDQoL) survey domains, and improved London Evaluation of Illness (LEVIL) scores; (4) reduced restless leg syndrome by 10 percent or more; and (5) reduced rate of subsequent therapeutic interventions such as reduced need for and use of erythropoietin stimulating agents (ESAs), iron, and insulin. The applicant supported these claims with seven published papers, one paper accepted for publication, and one poster. Several of the studies were secondary analyses of the same trial data.

With respect to the claim that THERANOVA decreases the number of future hospitalizations, the applicant noted that emergent need for hospitalization can be a serious and life-threatening event, especially for medically-fragile populations, and that hospitalization is a frequent and costly occurrence for the ESRD population. The applicant stated that an estimated 792,643 HD patient hospitalizations occur every year,[91] with roughly 40 percent of new dialysis patients averaging nearly two hospitalizations per year.[92] The applicant also asserted that ESRD patients often have health impairments associated with their condition and other comorbidities that put them at greater risk for

[85] As noted in the CY 2021 ESRD PPS final rule, we did not find the submitted evidence and public comments sufficient in meeting the substantial clinical improvement ''totality of the circumstances'' criterion at § 412.87(b)(1)(i). Therefore, we determined that THERANOVA did not qualify for the TPNIES at that time (85 FR 71457).

[86] Baxter. Theranova 400/500 Instructions For Use. N50 648 rev 003, 2017–05–29.

[87] Yilmaz MI, Carrero JJ, Axelsson J, Lindholm B, Stenvinkel P: Low-grade inflammation in chronic kidney disease patients before the start of renal replacement therapy: sources and consequences. Clin Nephrol 68:1– 9, 2007.

[88] Stenvinkel P. Can treating persistent inflammation limit protein energy wasting? Semin Dial. 2013;26(1):16–19. doi:10.1111/sdi.12020.

[89] Akchurin OM, Kaskel Fl. *Update on inflammation in chronic kidney disease.* Blood Purif 2015; 39:84–92.

[90] Alvarez L, et al. Intradialytic Symptoms and Recovery Time in Patients on Thrice-Weekly In-Center Hemodialysis: A Cross-sectional Online Survey, Kidney Med. 2020;2(2)125–130.

[91] The applicant's information on the number of hospitalizations is based on a Moran Company analysis of the following sourced figure: 'Average hospitalization rate' of hemodialysis patients captured from the United States Renal Data System (USRDS), 2020 Annual Data Report (ADR), End Stage Renal Disease, Chapter 4: Hospitalization, Figure 4.1a Adjusted hospitalization rates in prevalent Medicare beneficiaries with ESRD by treatment modality, 2009–2018.

[92] Nissenson AR, Improving Outcomes for ESRD Patients: Shifting the Quality Paradigm. CJASN Feb 2014, 9 (2) 430–434; DOI: 10.2215/CJN.05980613 *https://doi.org/10.2215/CJN.05980613.*

hospitalization, and at greater risk for adverse outcomes once hospitalized. The applicant stated that, for example, a recent study found that hospitalized ESRD patients on maintenance dialysis had higher odds of mortality after cardiopulmonary resuscitation (odds ratio, 1.24; 95 percent CI, 1.11 to 1.3; p < 0.001), compared to the general patient population.[93] The applicant explained that the frequency and severity of hospitalizations in the ESRD patient population adds urgency to adopting innovative technologies that can help prevent hospitalization and associated morbidity and mortality.

To support its claim that the use of THERANOVA decreases the number of future hospitalizations, the applicant referred to a poster by Tran et al. (2021), which was an abstract of a secondary analysis of a prospective, open-label, randomized controlled trial[94] of 172 patients (86 THERANOVA; 85 high-flux HD (HF–HD), with 1 patient not treated). As a post hoc analysis of a randomized controlled trial, the applicant stated that the objective of the study was to evaluate the association of HDx with the THERANOVA dialyzer with hospitalization rates, as compared to conventional HD. The applicant stated that patients were randomized and treated with either Theranova 400 or a conventional high-flux dialyzer in 21 U.S. study centers. The applicant noted that hospitalization was defined by the occurrence of any serious adverse event containing a hospitalization admission date, hospitalization rate was defined by treatment as total number of hospitalizations divided by total person-years of follow-up, and hospital length of stay was defined as number of days between admission and discharge. The applicant stated that this study found that the rate of hospitalizations for patients using THERANOVA was statistically significantly lower—45 percent—than those using HF–HD (IRR = 0.55; p = 0.0495).[95]

The applicant also referred to a multi-center, observational retrospective, cohort study by Molano-Triviño et al. (2022) that used propensity score matching assignment methods for 1,098 patients (534 HF–HD; 564 HDx with THERANOVA). The applicant stated that the objective of the study was to evaluate clinical effectiveness of THERANOVA versus HF–HD dialyzers, in terms of hospitalization rate and duration, cardiovascular event rate and survival in a HD cohort in Colombia. The applicant stated that adult HD patients (>90 days in HD) at Baxter Renal Care Services Colombia were included between September 1, 2017 to November 30, 2017, with follow-up until 2 years. The applicant noted that inverse probability of treatment weighting on the propensity score was used to balance comparison groups on indicators of baseline socio-demographic and clinical characteristics, and that the investigators compared rates and duration of hospitalization and cardiovascular events using a negative binomial regression to estimate weighted incidence rate ratios (IRRs). The applicant stated that this study found a statistically significant lower hospitalization rate in the THERANOVA group, compared to the HF–HD group (IRR HDx with THERANOVA/HF–HD: 0.82, 95 percent CI 0.69 to 0.98; p=0.03), without differences in hospitalization duration or survival.[96]

The applicant also referred to two other papers to further support reductions in hospitalization and medication utilization. According to the applicant, Sanabria et al. (2021) was a multi-center, observational prospective cohort study of 81 patients (Year 1, HF–HD; Year 2, HDx with THERANOVA). In this study across 3 clinics, the applicant noted that 175 patients with ESRD on chronic HD were originally recruited, and 23 did not meet the eligibility criteria. The applicant stated that patients received HF–HD for at least 1 year and then switched to HDx and were followed up for 1 year. The applicant stated that patients were excluded if they discontinued therapy, changed provider, underwent kidney transplant, recovered kidney function, or changed to PD, another dialyzer, or another renal clinic. The applicant noted that only 81 patients were eligible for analysis because 71 patients were lost to follow-up. The applicant asserted that the study results demonstrated that the rate of hospitalizations per patient-year was lower twelve months after switching to HDx, from 0.77 (95 percent CI: 0.60–0.98, 61 events) to 0.71 (95 percent CI: 0.55–0.92, 57 events), p=0.6987. The applicant also reported that the study results demonstrated significantly reduced hospital day rate per patient-year, from 5.94 days in the year prior to switching compared with 4.41 days after switching (p=0.0001).[97]

The applicant also cited Ariza et al. (2021), which the applicant noted analyzed the same study sample of 81 patients as Sanabria et al. (2021),[98] discussed previously in this section, with the stated objective of examining new evidence linking HDx using THERANOVA with hospitalizations, hospital days, medication use, costs, and patient utility. The applicant stated that this retrospective study utilized data from the Renal Care Services medical records database in Colombia from 2017 to 2019. The applicant noted that the study data included years on dialysis, hospitalizations, medication use, and QoL measured by the KDQoL survey at the start of HDx, and 1 year after HDx. The applicant stated that generalized linear models were run comparing patients before and after switching to HDx. The applicant asserted that the study results demonstrated that HDx was also significantly associated with lower hospital days per year (5.94 on HD vs. 4.41 on HDx), although not with the number of hospitalizations. The applicant stated that the results showed that HDx was statistically significantly associated with reduced hospitalization days.[99]

With respect to the claim that THERANOVA is associated with improved recovery time by up to 2 hours, the applicant stated that the treatment intensity and recovery time for patients on HD is a significant burden. The applicant explained that patients might receive in-center HD 3 days a week for 3 to 5 hour sessions, or home HD. The applicant noted that following treatment, there is often a prolonged period before a patient recovers to pre-treatment function and energy levels, with many patients reporting that they feel tired and in need

[93] Saeed F, Adil MM, Malik AA, Schold JD, Holley JL, Outcomes of In-Hospital Cardiopulmonary Resuscitation in Maintenance Dialysis Patients. JASN Dec 2015, 26 (12) 3093–3101; DOI: 10.1681/ASN.2014080766 *https://doi.org/10.1681/ASN.2014080766.*

[94] Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[95] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[96] Molano AP, Hutchison CA, Sanchez R, Rivera AS, Buitrago G, Dazzarola MP, Munevar M, Guerrero M, Vesga JI, Sanabria M, Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[97] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[98] Ibid.

[99] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

of rest or sleep. The applicant cited an estimate that 40 to 80 percent of patients receiving chronic HD face post-dialysis fatigue.[100] The applicant also noted that patients who were highly fatigued had a significantly higher risk of adverse cardiovascular events (hazard ratio: 2.17; p <0.01).[101] The applicant referred to the Dialysis Outcomes and Practice Patterns Study (DOPPS), which analyzed over 6,000 HD patients from 12 countries in Europe, Japan, Canada, and the U.S. The applicant noted that 25 percent of patients required more than 6 hours of recovery time, and that patient-reported recovery time was positively associated with rates of first hospitalization (adjusted hazard ratio [AHR] per additional hour of recovery time [RT], 1.03; 95 percent CI, 1.02–1.04) and all-cause mortality (AHR, 1.05; 95 percent CI, 1.03–1.07).[102] The applicant stated that improving recovery time is not only critical to averting hospitalization and increased risk of mortality, but also ensures that ESRD patients have meaningful QoL improvements.

To support its claim of improved recovery time, the applicant referred to a single-center, single-arm, observational, retrospective, cohort study by Bolton et al. (2021) of 58 patients with HF–HD at baseline who switched to THERANOVA. The applicant stated that a dialysis unit performed regular assessments of patient-reported symptom burden, using the POS–S Renal Symptom questionnaire and the ''Recovery time from last dialysis session'' question as part of routine patient focused care. The applicant noted that of the 90 people who initially agreed to provide patient reported outcome measures (PROMs) data, the number of participants providing data at 3, 6, 9, and 12 months were 80, 72, 68, and 59 respectively. The applicant concluded that a sustained clinically relevant reduction in post-dialysis recovery time was observed following the therapy switch. The applicant stated that the study results demonstrated that the percentage of patients reporting a recovery time greater than 360 minutes decreased from 36 percent at baseline to 26 percent, 14 percent, 14 percent, and 9 percent at 3, 6, 9, and 12 months, respectively. The applicant noted that additionally, there was a statistically significant improvement in median recovery time from a baseline of 210 minutes (IQR 7.5–600) to 60 minutes after 6 months (0–210; p = 0.002), 60 minutes after 9 months (0–225; p < 0.001), and 105 minutes after 12 months (0–180; p = 0.001).[103]

With respect to the claim that THERANOVA is associated with improved QoL, as indicated by reduced pruritus, improvement in two KDQoL survey domains, and improved London Evaluation of Illness (LEVIL) scores, the applicant described the background and significance of each indicator. The applicant noted that that pruritus can be uncomfortable and significantly interfere with ESRD patients' daily living activities. The applicant asserted that pruritus that is severe or chronic can prevent ESRD patients from sleeping normally,[104] and that in addition to causing sleep loss, pruritus can also cause anxiety and depression.[105] The applicant also noted that prolonged scratching of itchy skin also leads to skin injury, scarring, and infection.[106]

The applicant also explained that one of the most commonly used tools to assess kidney disease QoL in the U.S. is the KDQoL[107] patient survey, which assesses patients' physical and mental well-being, the burden of kidney disease, treatment-associated symptoms and problems, and the effects of kidney disease on daily life. The applicant noted that the survey assesses a patient's ability to accomplish desired tasks, levels of depression and anxiety, the ability to participate in social activities, and some daily life activities.

The applicant also referenced the LEVIL survey, which measures patient-reported outcomes and evaluates well-being, energy level, sleep quality, bodily pain, appetite, and shortness of breath. Per the applicant, the survey is validated, and scores are correlated with acute hospital admissions, abnormal fluid status, and vascular access events.[108]

To support its claim of improved pruritus and improvement in two KDQoL survey domains, the applicant referred to a prospective, open-label, randomized control trial by Lim, Park, et al. (2020). This study randomized patients to either Theranova 400 or a high-flux dialyzer. Forty-nine HD patients (24 using THERANOVA; 25 using a high-flux dialyzer) completed the study. Per the applicant, QoL was assessed at baseline and after 12 weeks of treatment using the KDQoL Short Form-36, and pruritus was assessed using a questionnaire and visual analog scale. The applicant stated that the study concluded that laboratory markers, including serum albumin, did not differ between the two groups after 12 weeks, though removals of kappa and lambda free light chains were greater for THERANOVA than high-flux dialyzer. The applicant noted that the results showed that the THERANOVA group had lower mean scores for morning pruritus distribution (1.29 ± 0.46 vs. 1.64 ± 0.64, p = 0.034) and frequency of scratching during sleep (0.25 ± 0.53 vs. 1.00 ± 1.47, p = 0.023), compared to the high-flux group. The applicant also stated that in the same study, the THERANOVA group also had statistically significant higher scores (indicating better QoL) in KDQoL domains for physical functioning (75.2 ± 20.8 vs. 59.8 ± 30.1, p = 0.042) and physical role (61.5 ± 37.6 vs. 39.0 ± 39.6, p = 0.047), compared to the high-flux group.[109]

To support its claim of improved QoL scores, the applicant referred to a study by Penny et al. (2021). According to the applicant, this was a single-center interventional pilot study with 28 patients established on maintenance HD. The single-arm study consisted of 2-week observation (baseline at conventional HF–HD) followed by 12 weeks of HDx. The study also had an extension phase; where patients had a 2-week baseline period, followed by 24 weeks of HDx, and then an 8-week washout period in which patients returned to HF–HD to assess the presence of any carryover effect. The applicant stated that health-related quality of life (HRQoL) was assessed

[100] Bossola M, et al. Fatigue is associated with increased risk of mortality in patients on chronic hemodialysis. Nephron 2015; 130:113–118.

[101] Koyama H, Fukuda S, Shoji T, Inaba M, Tsujimoto Y, Tabata T, Okuno S, Yamakawa T, Okada S, Okamura M, Kuratsune H, Fujii H, Hirayama Y, Watanabe Y, Nishizawa Y, Fatigue Is a Predictor for Cardiovascular Outcomes in Patients Undergoing Hemodialysis CJASN Apr 2010, 5 (4) 659–666; DOI: 10.2215/CJN.08151109.

[102] Rayner HC, et al. Recovery time, quality of life, and mortality in hemodialysis patients: The Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis 2014; 64:86–94.

[103] Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas. 2021;12:315–321 *https://doi.org/10.2147/PROM.S325016.*

[104] Mayo Clinic, Itchy skin (pruritus), available at *https://www.mayoclinic.org/diseases-conditions/itchy-skin/symptoms-causes/syc-20355006.*

[105] Ibid.

[106] Ibid.

[107] RAND Corporation, Kidney Disease Quality of Life Instrument (KDQOL), available at *https://www.rand.org/health-care/surveys_tools/kdqol.html.*

[108] Pittman Z, et al. Collection of daily patient reported outcomes is feasible and demonstrates differential patient experience in chronic kidney disease. Hemodialysis International, 2017; 21:265–273.

[109] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622-z.

using the dynamic PROM instrument, LEVIL, twice weekly. The applicant noted that 22 patients completed all study procedures to contribute to the full 12-week analysis. The applicant asserted that the study results demonstrated that 73 percent of participants who had low overall health-related QoL at baseline with HF–HD (mean, 51.5 ± 10.2; range, 36.1–69.3) had a statistically significant improvement at 8 weeks after switching to HDx (mean, 64.6 ± 16.2; p=0.001) and at 12 weeks (67.2 ± 16.9; p=0.001). The applicant stated that the study also found that all participants had a statistically significant improvement in 'feeling washed out/drained' from baseline with HF–HD (mean, 40.3 ± 20.5; range, 8.7–67.4) to HDx at 8 weeks (59.9 ± 22.8; p=0.001) and at 12 weeks (64.7 ± 19.6; p < 0.001). The applicant noted that likewise, 73 percent of study participants assessed on their 'feeling of general well-being' had a statistically significant improvement from baseline with HF–HD (mean, 43 ± 14.1; range, 19.7–69.5) to HDx at 8 weeks (65.2 ± 21.9; p < 0.001) and at 12 weeks (66.3 ± 17.7; p=0.002). Additionally, the applicant stated that 73 percent of study participants who experienced poor 'sleep quality' had a statistically significant improvement from baseline with HF–HD (37.2 ± 20.1; range, 7.2–66.2) after 4 weeks with HDx (mean, 52.8 ± 26.7; p=0.01), and continually improved at 8 weeks (57 ± 22.2; p=0.002) and 12 weeks (61.7 ± 24.5; p <0.001).[110]

With respect to the claim that THERANOVA is associated with reducing restless leg syndrome (RLS) by 10 percent or more, the applicant stated that RLS is another common and debilitating side effect of long-term dialysis. The applicant noted that an estimated 6.6 percent to 62 percent of patients on long-term dialysis therapy suffer from RLS,[111] with one study suggesting 20 to 25 percent of ESRD patients demonstrated overt (moderate to severe) RLS.[112] The applicant asserted that extreme discomfort of RLS worsens during periods of physical inactivity and at night,[113] contributing to sleep loss and sleep deprivation in ESRD patients, and that loss of sleep carries over into the day for many patients, leaving them feeling lethargic and preventing them from fully engaging in daily activities. The applicant also noted that a study found that RLS among HD patients is associated with a significant increase in new cardiovascular events, that these events increased with the severity of RLS, and that HD patients with RLS had a higher risk of mortality than their non-RLS peers.[114] The applicant also described an additional study that found RLS was associated with significantly higher risk of developing cardiovascular events, strokes, and all-cause mortality among ESRD patients.[115] The applicant explained that RLS is treated with many medications such as dopamine antagonists, benzodiazepines, anti-epileptics, iron dextran, Vitamin C, and intradialytic aerobic exercise—all of which produce side effects and only provide limited improvement in RLS symptoms.[116] The applicant stated that medical interventions for RLS in dialysis populations have not been particularly effective, are costly, and may contribute to polypharmacy and adverse drug reactions in a population already at risk.[117]

To support its claim that THERANOVA is associated with reducing RLS, the applicant referred to a multi-center, observational prospective cohort study by Alarcon et al. (2021) which assessed 992 individuals with HF–HD at baseline, who switched to THERANOVA and were observed over a 12-month period. The applicant explained that changes in KDQoL 36-Item Short Form Survey domains, Dialysis Symptom Index (DSI), and RLS 12 months after switching to THERANOVA were compared with the patient baseline responses on high-flux dialyzers. Per the applicant, the study found a significant decrease in the proportion of patients diagnosed with RLS from 22.1 percent at baseline to 12.5 percent at 6 months, and 10 percent at 12 months (p < 0.0001). Additionally, the applicant stated that a post hoc comparison showed statistically significant differences between each pair of repeated observations (baseline vs. 6 months: p <0.0001; baseline vs. 12 months: p <0.0001; 6 vs. 12 months: p=0.003).[118]

With respect to the claim that THERANOVA reduces the rate of subsequent therapeutic interventions, such as the use of ESAs, iron, and insulin, the applicant stated that almost all dialysis patients and those with CKD experience anemia as a side effect of their treatment, which contributes negative clinical outcomes such as weakness, irregular heartbeat, shortness of breath, dizziness and lightheadedness, chest pain, and headaches.[119] The applicant stated that anemia significantly impairs QoL for dialysis patients and requires additional treatment, and that ESAs are a widely used treatment that mitigates anemia by enabling the body to produce more red blood cells. The applicant asserted that reductions in ESA treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.

With regard to iron supplementation, the applicant noted that iron supplements are another important treatment for patients with renal failure and anemia. The applicant explained that iron deficiency occurs more frequently among patients with ESRD because of an increase in external losses of iron, a decreased ability to store iron in the body, and potential deficits in intestinal iron absorption.[120] The applicant asserted that reductions in iron treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.[121]

Finally, with regard to insulin use, the applicant stated that diabetes is a common comorbidity in ESRD

[110] Penny J., Jarosz P., Salerno F., Lemoine S., McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2021.05.010*.

[111] Kavanagh D., et al. Restless legs syndrome in patients on dialysis Am J. Kidney Dis. 2004 May;43(5):763–71.

[112] Winkelman J.W., Chertow G.M., Lazarus J.M.. Restless legs syndrome in end-stage renal disease. Am J. Kidney

[113] Kavanagh D., et al. Restless legs syndrome in patients on dialysis Am J. Kidney Dis. 2004 May;43(5):763–71.

[114] La Manna G., et al. Restless legs syndrome enhances cardiovascular risk and mortality in patients with end-stage kidney disease undergoing long-term haemodialysis treatment. Nephrol Dial Transplant.2011;26(6):1976–83.

[115] Lin C.H., et al. Restless legs syndrome is associated with cardio/cerebrovascular events and mortality in end-stage renal disease. Eur J. Neurol. 2015;22(1):142–9.

[116] Gopaluni S., Sherif M., Ahmadouk N.A. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690.

[117] Gopaluni S., Sherif M., Ahmadouk N.A. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690.

[118] Alarcon J.C., Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[119] Mayo Clinic's overview of anemia, available at *https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360*.

[120] Fishbane S., Maesaka J.K., Iron management in end-stage renal disease, American Journal of Kidney Diseases, Volume 29, Issue 3, 1997, Pages 319–333, ISSN 0272–6386, Accessed at: *https://doi.org/10.1016/S0272-6386(97)90192-X*.

[121] Estimated cost to Medicare based on The Moran Company, an HMA Company analysis calculated using 2020 ESRD claims with IV iron valued at ASP+6%.

patients,[122] and many ESRD patients require additional insulin administration. The applicant asserted that through reductions in insulin use, Medicare could realize cost savings of $3,949 annually per diabetes patient.[123]

To support its claim of reduced rate of subsequent therapeutic interventions such as reduced need for and use of ESAs, iron, and insulin, the applicant referred to three sources. The first source, Lim, Jeon, et al. (2020), was a secondary analysis of a prospective, open-label, randomized controlled trial by Lim, Park, et al. (2020).[124] Lim, Park, et al. (2020) was previously described. According to the applicant, the primary outcome of the secondary analysis was the change in erythropoietin resistance index (ERI; U/kg/wk/g/dL) between baseline and 12 weeks. The applicant stated that the study found statistically significant decreases in ESA dose, weight-adjusted ESA dose, and erythropoiesis resistance index for THERANOVA patients, compared to the high-flux dialyzer group at 12 weeks ($p < 0.05$). The applicant also stated that there was a statistically significant higher serum iron level in the THERANOVA group at 12 weeks (iron [7g/dL]: 72.1 ± 25.4 vs. 55.9 ± 25.0), ($p=0.029$), indicating an improvement in iron metabolism as a potential clinical marker for the reduced need of iron supplementation.[125]

The applicant also referred to the Sanabria et al. (2021) study, previously described, of 81 patients (Year 1, HF–HD; Year 2, HDx with THERANOVA). The applicant stated the study concluded that there was a statistically significant reduction in the mean dose of ESA after switching from HF–HD to HDx with THERANOVA ($p=0.0361$).[126] The applicant also stated that the study found a statistically significant reduction in the mean dose of intravenous iron from 73.46 mg/month with HF–HD to 66.36 mg/month with HDx with THERANOVA ($p=0.003$).[127]

Finally, the applicant referred to the Ariza et al. (2021) study, described previously in this section of the proposed rule. The applicant stated that study authors found a statistically significant reduction in the dosage per patient per year of ESA in international units from 181,318 with HF–HD (95 percent CI: 151,647– 210,988) to 168,124 with HDx with THERANOVA (95 percent CI: 138,452–197,794; $p <0.01$) as well as a statistically significant reduction in dosage per patient per year of iron in milligrams from 959 with HF–HD (95% CI: 760–1158) to 759 with HDx (95 percent CI: 560–958; $p <0.01$).[128] The applicant also asserted that the study found a statistically significant reduction in dosage per patient per year of insulin in international units from 5383 with HF–HD (95 percent CI: 3274–7490) to 3434 with HDx with THERANOVA (95 percent CI: 1327–5543; $p <0.01$).[129]

The applicant also referred to CMS' final determination and public comments regarding its CY 2021 TPNIES application, as summarized in the CY 2021 ESRD PPS final rule (85 FR 71453 through 71458). The applicant stated that stakeholders largely provided favorable comments and supported TPNIES approval for THERANOVA. The applicant noted that in particular, physicians who used THERANOVA and had direct patient experience with the product strongly supported the application.[130] The applicant also noted that some stakeholders, however, expressed concerns about THERANOVA's CY 2021 TPNIES application. Specifically, the applicant stated that commenters noted that the supporting studies had small sample sizes that did not represent the U.S. patient population, and that the duration of the studies was too short. The applicant also stated that some stakeholders expressed a belief that HDx with THERANOVA may result in decreased albumin levels, potentially causing harm to patients. The applicant asserted that with the updated and additional information provided in its CY 2023 application, the applicant has addressed these concerns.

The applicant asserted that all substantial clinical improvement claims included in its CY 2023 application are now supported by at least one study that has undergone full peer review and has been published, or accepted for publication and is being prepared for publishing. The applicant explained that the application's supporting studies feature statistically significant findings and have a range of appropriate sample sizes, such as Molano-Triviño et al., n=1,098,[131] and Alarcon et al., n=992,[132] previously described. The applicant explained that additionally, many studies evaluated THERANOVA's impacts over an extended period, including year-long evaluations after patients transitioned from conventional therapy to HDx therapy, for example, Sanabria et al.[133] and Ariza et al.,[134] previously described. The applicant stated that it considers the studies supporting the application and their findings to be applicable and generalizable to the U.S. Medicare population, and that this generalizability is bolstered by the additional U.S.-specific information and findings. The applicant asserted that while it does not believe that results in sample populations would significantly differ from results in the U.S. patient population, the application also now includes additional evidence that

[122] Approximately one in three adults with diabetes also have CKD. See CDC, Diabetes and Chronic Kidney Disease, *https://www.cdc.gov/diabetes/managing/diabetes-kidney-disease.html.*

[123] Average cost per patient for insulin taken from KFF report on Part D spending, available at *https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/.*

[124] Lim J.H., Park Y., Yook J.M., et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[125] Lim J.H., Jeon Y., Yook J.M., et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124–x.

[126] Sanabria R.M., Hutchison C.A., Vesga J.I., Ariza J.G., Sanchez R., Suarez A.M. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[127] Ibid.

[128] Ariza, J.G., Walton, S.M., Suarez, A.M., Sanabria, M., Vesga, J.I. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[129] Ibid.

[130] See for example, Dr. Peter Stenvinkel (Karolinska University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0038;* Dr. Vincenzo Cantaluppi (Novara University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0066;* Dr. Colin Hutchison (Central Hawkes Bay Health Centre) at *https://beta.regulations.gov/comment/CMS-2020-0079-0065;* Dr. Andrew Davenport (Royal Free Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0037;* Dr. Mario Cozzolino (University of Milan) at *https://beta.regulations.gov/comment/CMS-2020-0079-0062;* Dr. Jang-Hee Cho (Kyungpook National University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0061.*

[131] Molano A.P., Hutchison C.A., Sanchez R., Rivera A.S., Buitrago G., Dazzarola M.P., Munevar M., Guerrero M., Vesga J.I., Sanabria M., Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[132] Alarcon J.C., Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[133] Sanabria R.M., Hutchison C.A., Vesga J.I., Ariza J.G., Sanchez R., Suarez A.M. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328

[134] Ariza, J.G., Walton, S.M., Suarez, A.M., Sanabria, M., Vesga, J.I. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

directly addressed U.S. patients, including: a new study on U.S. hospitalization rates; new survey data from U.S. patients, health care providers, and payers, which demonstrated THERANOVA's value, clinical improvements, and QoL enhancements; [135] and includes new testimonials in support of the TPNIES application for THERANOVA from U.S. kidney care providers: a nephrologist with 10 years of experience, dialysis nurse with 15 years of experience, and a pediatric dialysis nurse practitioner with over 10 years of experience. The applicant noted that the survey data came from three separate double-blinded surveys presented to each respondent group with information about THERANOVA's benefits and then assessed reactions—including patients' interest in switching from their current HD therapy to THERANOVA's HDx therapy, the likelihood that health care providers would recommend THERANOVA to patients and colleagues, and payers' evaluations of THERANOVA's potential to generate value for their health plans and patient enrollees. The applicant noted that overall, patients overwhelmingly wanted to use THERANOVA, health care providers strongly indicated that they would recommend THERANOVA to patients and peers, and payers identified several of THERANOVA's improvements as generating value. The applicant asserted that the peer-validated studies, and additional evidence that further addresses the U.S. patient population, provide the support necessary to conclude that THERANOVA is a substantial clinical improvement over existing technologies.

The applicant also stated that in addition to THERANOVA's demonstrated effectiveness, additional evidence demonstrates THERANOVA's safety. The applicant explained that in the time since it submitted the CY 2021 TPNIES application to CMS, FDA reviewed THERANOVA's randomized, controlled clinical IDE trial and additional evidence supporting THERANOVA's safety and effectiveness, and granted marketing authorization. The applicant stated that the IDE trial demonstrated that THERANOVA's HDx therapy provides superior removal of harmful LMMs while maintaining adequate serum albumin levels.[136] The applicant noted that FDA's comprehensive review and subsequent approval of THERANOVA establishes THERANOVA's safety and effectiveness for its intended use: treatment of chronic kidney failure.

(b) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant, we note that the applicant submitted the full, published peer-reviewed papers for several of the abstracts, posters, and incomplete manuscripts that were previously submitted with its CY 2021 TPNIES application,[137] [138] [139] [140] [141] [142] and the remaining evidence submitted with the CY 2023 application was new. We have identified the following concerns regarding THERANOVA and the substantial clinical improvement eligibility criteria for the TPNIES. We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether THERANOVA meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

With respect to the applicant's claim that THERANOVA leads to reduced hospitalization rates, we note that the applicant included studies from the previous submission and supplemented with newer studies, such as the Tran et. al. (2021) poster abstract. We note that the poster abstract was a post hoc analysis of a previous open-label study,[143] which had an average follow-up period of 4.5 months in the THERANOVA group. We question whether this short time period is sufficient to see changes in hospitalization from interventions aimed at increasing clearance of uremic toxins. It may be helpful to see if this outcome is sustained in longer term follow-up.[144]

We also note that, although authors in the Molano et. al. (2022) study used inverse probability treatment weighting (IPTW), the study was unblinded and could influence treatment decisions in the group using the THERANOVA dialyzer. Moreover, we note that patients seemed healthier in the THERANOVA arm, and had more fistulas, fewer catheters, and higher Karnofsky indices. We also note that the THERANOVA arm had more intensive dialysis at baseline and throughout the duration of the study (Kt/V of 1.7 vs. 1.6), suggestive of more intensive small molecule clearance and more intensive dialysis overall. Therefore, it is unclear whether the outcome differences between the two arms could be due to factors other than the dialyzer type. We question whether IPTW would be sufficient to overcome these biases, especially the Kt/V bias, which persisted even after the baseline period.[145]

In addition, we note that the studies by Ariza et al. (2021) [146] and Sanabria et al. (2021),[147] using the same study sample population, were limited by absence of a control group, and had non-significant differences in hospitalization rate between baseline HF–HD and after switching to HDx: 0.77

[135] Patient Preference for a Future Dialyzer Study, prepared by Beghou Consulting on behalf of Baxter International. Survey results; December 2021.

[136] Weiner D., et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[137] Alarcon J.C., Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[138] Ariza, J.G., Walton, S.M., Suarez, A.M., Sanabria, M., Vesga, J.I. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[139] Bolton S., Gair R., Nilsson L.G., Matthews M., Stewart L., McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S325016.*

[140] Lim J.H., Jeon Y., Yook J.M., et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124–x.

[141] Lim J.H., Park Y., Yook J.M., et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[142] Sanabria R.M., Hutchison C.A., Vesga J.I., Ariza J.G., Sanchez R., Suarez A.M. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[143] Weiner D., et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[144] Tran H., Falzon L., Bernardo A., Beck W., Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[145] Molano A.P., Hutchison C.A., Sanchez R., Rivera A.S., Buitrago G., Dazzarola M.P., Munevar M., Guerrero M., Vesga J.I., Sanabria M., Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[146] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[147] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R., Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

(95 percent CI: 0.60–0.98, 61 events) to 0.71 (95 percent CI: 0.55–0.92, 57 events), p=0.6987.

With respect to the applicant's claim that THERANOVA leads to improved QoL, we note that in the study by Lim, Park, et al. (2020), it is unclear if these findings could result from chance alone, when considering the many QoL outcomes examined, due to multiple-hypothesis testing concerns. In particular, we note that differences associated with use of THERANOVA were statistically significant in only 2 out of 26 QoL outcomes assessed, and in both cases the p-value was greater than 0.04. We also note that although the THERANOVA group had lower mean scores for morning pruritus distribution (p=0.034), there was a non-significant difference in afternoon pruritis distribution between the two groups (p=0.347).[148]

Overall, we note that most of studies in the updated evidence submitted for the CY 2023 application are open-label and observational, which may potentially bias results. We also note that many of the studies are single-arm studies that do not employ a control group, which may make it difficult to determine if observed improvements in clinical outcomes are due to the use of THERANOVA or if the improvements may have also occurred with previously available dialysis membranes.[149] [150] [151] [152]

We are inviting public comment as to whether THERANOVA meets the TPNIES substantial clinical improvement criteria.

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant did not address this criterion within its application. However, THERANOVA does not meet the definition of a capital-related asset, as defined in § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation.[153] We welcome comments on THERANOVA's status as a non-capital related asset.

d. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2023

In this section of the proposed rule, we provide a table that identifies the one item that was approved for the TPNIES for CY 2022 [154] and which is still in the TPNIES payment period, as specified in § 413.236(d)(1), for CY 2023. CMS will continue paying for this item using the TPNIES for CY 2023. This table also identifies the item's HCPCS coding information as well as the payment adjustment effective date and end date.

TABLE 14: Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
E1629	Tablo hemodialysis system for the billable dialysis service	1/1/2022	12/31/2023

e. Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products for CY 2023

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved *Korsuva*™ (difelikafalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,[155] dated March 15, 2022, and available at: *https://www.cms.gov/files/document/r11295CP.pdf*.

In this section of the proposed rule, we provide a table that identifies the one new renal dialysis drug that was approved for the TDAPA effective in CY 2022, and for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2023. This table also identifies the product's HCPCS coding information as well as the payment adjustment effective date and end date.

[148] Lim JH, Park Y., Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[149] Bolton S., Gair R., Nilsson LG, Matthews M., Stewart L., McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S325016*.

[150] Penny J., Jarosz P., Salerno F., Lemoine S., McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2021.05.010*.

[151] Alarcon JC, Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[152] Lim JH, Jeon Y., Yook JM, et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124–x.

[153] See also: CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*.

[154] 86 FR 61889 through 61906.

[155] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022.

TABLE 15: Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	4/1/2022	3/31/2024

D. Request for Information About Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After Transitional Drug Add-On Payment Adjustment (TDAPA) Period Ends

1. Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at 42 CFR 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. 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 are commercially available so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all of the drugs and biological products within these categories because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

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 that if a new renal dialysis injectable or IV product falls within an existing functional category, the new injectable drug 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. We noted in that rule that the ESRD bundled market basket updates the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products.

We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal dialysis injectable or IV product does not fall within an existing 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 codified 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 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. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, 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.

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, 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. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by the 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, effective January 1, 2020.

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the base rate will not be modified. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological

product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification (83 FR 56935).

For the complete history of the TDAPA policy, including the pricing methodology, please see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

2. Current Issues and Concerns of Interested Parties

In the CY 2019 ESRD PPS final rule, we discussed that a commenter stated concern over beneficiary access issues at the end of the TDAPA period. We responded by noting the drug or biological product will become eligible under the outlier policy after the TDAPA period if it is not considered to be a composite rate drug. We stated that we expect that if a beneficiary is responding well to a drug or biological product paid for using the TDAPA that they will continue to have access to that therapy after the TDAPA period ends (83 FR 56941). Since 2019, dialysis associations and pharmaceutical representatives have expressed concerns to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. They asserted that unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, they cautioned that uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA period. To date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. There have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result CMS does not yet have data on other drugs or biological products in order to evaluate the specific risks and access challenges that interested parties have raised.

As mentioned in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules, many commenters suggested a rate-setting exercise at the end of TDAPA for all new renal dialysis drugs and biological products. We responded by noting that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and there will be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. A central objective of the ESRD PPS and of prospective payment systems in general is for facilities to be efficient in their resource use.

We also note that price changes to the ESRD bundled payment are updated annually by the ESRDB market basket, which includes a pharmaceuticals cost category weight, as noted in section II.B.1.a.(1)(b) of this proposed rule. In addition, our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time relative to market basket growth for some high volume formerly separately billable renal dialysis drugs. Therefore, we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

3. Suggestions for Possible Methodologies for an Add-On Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products Within an Existing Functional Category

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(I) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas. In response to the patient access concerns discussed previously in this section of the proposed rule, we are considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We note that any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance payment under ESRD PPS. We are considering a number of methods that could be used to develop an add-on payment adjustment for these drugs and biological products. The methods presented below differ in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for a potential add-on payment adjustment. We note that under these potential options, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

- Reconcile the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products. For example, if the reduction in the cost of all formerly separately billable renal dialysis drugs and biological products per treatment excluding the renal dialysis drug or biological product that was paid for using the TDAPA is $5 and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, the add-on payment adjustment per treatment would be $10 minus $5, which is $5. The reductions in formerly separately billable renal dialysis drug and biological products expenditures

per treatment would be calculated by using the difference between these expenditures in the most recent year with claims data available and these expenditures in the current base year for the ESRDB market basket, proposed to be CY 2020 in this rule. For example, if the rule year for which we are calculating the add-on payment adjustment is CY 2023 and the base year for the ESRDB market basket is CY 2020, the reduction in formerly separately billable renal dialysis drugs and biological products expenditures would be the difference between these expenditures in CY 2021 (the year with the most recent claims data) and those in CY 2020.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where such reduction can be empirically attributed to the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the utilization of the renal dialysis drug or biological product that was paid for using the TDAPA was found to be statistically associated with reduction in expenditure of one drug in an ESRD PPS functional category amounting to $1 per treatment, and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, the add-on payment adjustment per treatment would be $10 minus $1, which is $9.
- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs that fall into one or more ESRD PPS functional categories, where such expenditure reduction is data-driven, based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA. Such a data-driven determination would be made by CMS. For example, if the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10 and the reduction in the expenditure for other clinically related formerly separately billable renal dialysis drugs is $0.50 per treatment, the add-on payment adjustment would be $10 minus $0.50, which is $9.50.
- Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the per treatment cost of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, this would be the amount of the add-on payment adjustment.

4. Request for Information on an Add-On Payment Adjustment After the TDAPA Period Ends

We are considering options regarding an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends. We are issuing a request for information to seek feedback from the public on the following questions. When responding, please note the question to which your comment is addressing.

- Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS establish to determine which renal dialysis drugs or biological products would be included in the calculation for an add-on payment adjustment after the TDAPA period ends?
- If an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period is needed, are the methods discussed in section II.D.4 of this proposed rule sufficient to address the add-on payment adjustment?

++ Which method would be most appropriate?

++ Are there changes to the methodologies that CMS should consider to improve our ability to align payment for renal dialysis services with resource utilization? Please provide as much detail as possible.

++ Are there other methodologies that CMS should consider? Please provide as much detail as possible.

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. Any potential payment policies related to this RFI would be proposed through a separate notice and comment rulemaking. We look forward to receiving feedback on these topics, and note that responses to the RFI should focus on how the suggestions could be applied to the ESRD PPS. Data to support any proposed approaches will be extremely important, so please include any data that supports your comments.

E. Requests for Information on Health Equity Issues Within the ESRD PPS With a Focus on the Pediatric Payment

1. Background

CMS is committed to achieving equity in health care for our beneficiaries by recognizing and working to redress inequities in our policies and programs that serve as barriers to access to care and quality health outcomes. In this proposed rule, ''health equity means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [156]

Significant and persistent inequities in health care outcomes exist in the United States. Belonging to a racial or ethnic minority group; living with a disability; being a member of the LGBTQ+ community; living in a rural area; or being near or below the Federal Poverty Level, are factors frequently associated with worse health outcomes.[157] [158] [159] [160] [161] [162] [163] [164] Numerous studies have shown that among Medicare beneficiaries, individuals belonging to a racial or ethnic minority group often experience delays in care, receive lower quality of care, report dissatisfactory experiences of care, and experience more frequent hospital readmissions and procedural complications than white patients and

[156] *https://www.cms.gov/pillar/health-equity.*

[157] Joynt KE, Orav E., Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[158] Lindenauer PK, Lagu T., Rothberg MB, et al. Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[159] Trivedi AN, Nsa W., Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[160] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[161] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[162] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[163] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[164] Poteat TC, Reisner SL, Miller M., Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

patients with a higher levels of income.[165] [166] [167] [168] [169] [170] When compared to FFS beneficiaries not receiving renal dialysis services, FFS beneficiaries receiving renal dialysis services are disproportionately young, male, disabled, Black/African-American, low income as measured by dually eligible Medicare and Medicaid status, and reside in an urban setting.[171]

a. Underserved Communities in the ESRD Medicare Population

During the TEP held in December 2021, CMS's ESRD data contractor provided data stratified by the following factors to TEP participants in order to identify subpopulations for which health disparities may exist among the ESRD population: sex, age, race/ethnicity, urban/rural residence, socioeconomic status proxy (combines both dual eligibility and receipt of premium subsidy for Part D), original reason for Medicare entitlement, and the Area Deprivation Index (ADI) for the beneficiary's residence (which also serves as a proxy for socioeconomic status). Definitions for these categories as well as relevant results, based on enrollment numbers in January 2020, are detailed below.

- Sex [172]—The ESRD PPS population was 58.7 percent male compared to 46.9 percent male in the non-ESRD Medicare population.
- Age [173]—The ESRD PPS population was younger than the non-ESRD Medicare population, in part because ESRD is a qualifying condition for Medicare, regardless of age, if the individual otherwise meets Social Security benefit qualifications.[174] Approximately 40 percent of the ESRD PPS beneficiary population was younger than 60 compared to 10 percent in the non-ESRD Medicare population.
- Original Reason for Medicare Entitlement—The ESRD Medicare population had a higher proportion of beneficiaries entitled to Medicare due to disability compared to the non-ESRD population. Forty-seven percent of the ESRD population was originally eligible for Medicare due to disability (with or without ESRD), compared to 21 percent for the non-ESRD Medicare population.[175]
- Race and Ethnicity [176]—Members of racial or ethnic minority groups comprised a larger proportion of the ESRD Medicare population compared to the non-ESRD Medicare population. This was especially true among Blacks/African-Americans who comprised 34.5 percent of the ESRD population, compared to 8.9 percent of the non-ESRD Medicare population.
- Urban and Rural Residency [177]—ESRD Medicare beneficiaries were more likely to reside in urban areas than the non-ESRD Medicare population. Approximately 84 percent of ESRD beneficiaries lived in urban areas, while approximately 79.6 percent of the non-ESRD Medicare population lived in urban areas.
- Socioeconomic status proxy [178]—42.5 percent of the ESRD Medicare population was dually eligible for Medicare and Medicaid as compared to 15.4 percent of the non-ESRD Medicare population. As compared to the non-ESRD Medicare population, ESRD Medicare beneficiaries were more likely to be enrolled in Medicare Part D (73 percent ESRD PPS as compared to 61 percent of non-ESRD Medicare beneficiaries). Among ESRD Medicare beneficiaries, Non-Hispanic White beneficiaries are less likely to be enrolled in Medicare Part D (70.0 percent Part D enrollment) compared to other groups (ranging from 72.3 to 77.2 percent enrolled in Part D).[179]
- ADI [180]—ESRD Medicare beneficiaries were more likely to be living in socioeconomically disadvantaged neighborhoods compared to non-ESRD Medicare beneficiaries, approximately 29 percent of the ESRD PPS population resided in the most disadvantaged ADI percentiles (76th to 100th percentile) compared to 19.2 percent of non-ESRD Medicare beneficiaries. ESRD beneficiaries who were socioeconomically disadvantaged were more likely to be enrolled in Medicare Part D than those less disadvantaged. Based on the demographics of the Medicare ESRD

[165] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[166] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[167] Singh JA, Lu X, Rosenthal GE, Ibrahim S., Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec; 73(12):2107–15.

[168] Rivera-Hernandez M., Rahman M., Mor V., Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[169] Joynt KE, Orav E., Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[170] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[171] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[172] Sex is derived from the Enrollment Database (EDB), and is categorized into male and female. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[173] Beneficiary age (in years) is measured at the beginning of each month, and is obtained from the Medicare beneficiary birth date variable in the EDB Record Identification Code (RIC) A Table. The following seven age groups are used for all relevant data presentation for this TEP: less than 12, 13–17, 18–44, 45–59, 60–69, 70–79, and 80. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[174] Section 226A of the Act; 42 CFR 406.13.

[175] ESRD beneficiaries are stratified into four mutually exclusive categories based on their original Medicare entitlement: (1) less than 65 years of age and had both ESRD and disability at time of enrollment; (2) less than 65 years of age and had ESRD at time of enrollment; (3) less than 65 years of age and were disabled at time of enrollment; and (4) those who aged into Medicare (and were diagnosed with ESRD after turning 65). Placeholder for TEP 4 Report.

[176] Beneficiary race and ethnicity information is derived from the Research Triangle Institute (RTI) race algorithm, as obtained from CMS Common Medicare Environment (CME) data. This data provides seven mutually exclusive categories: Non-Hispanic White, Black/African American, Asian or Pacific Islander, Hispanic, American Indian or Alaska Native, and Other/Unknown. Placeholder for TEP 4 Report.

[177] The Core-Based Statistical Area (CBSA) designations are used to determine urban or rural residency status. Beneficiaries whose county of residence is located within a CBSA are deemed urban residents. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[178] Among Medicare Part D enrollees, Medicare benefit status was derived from monthly enrollment status and low-income status in EDB. Both the beneficiary's dual eligibility status (whether the beneficiary was eligible for both Medicare and Medicaid in a given month) and Premium Subsidy status (whether the beneficiary was receiving any level of premium subsidy in a given month) were considered in determining the beneficiary's Medicare benefit status. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[179] This result is believed to be due to the fact non-white beneficiaries are more often dually eligible for Medicare and Medicaid compared to White beneficiaries. The low-income subsidies provided to dually eligible beneficiaries gives them the means to enroll in Part D, which is likely why this percentage is slightly higher for non-whites.

[180] ADI is a measure constructed by the Health Resources and Services Administration, and has been validated, refined and adapted by researchers at the University of Wisconsin, Madison, to rank neighborhoods (geographically localized communities within a larger cities, towns, suburbs or rural areas) by socioeconomic disadvantage, specifically factoring in income, education, employment, and housing quality. From these percentile rankings, six mutually exclusive categories of ADI Rankings are constructed with the 1st to 5th percentile being the least disadvantaged and 95th to 100th percentile being most disadvantaged. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

beneficiaries, it is clear that this population represents many individuals who belong to underserved communities, thus there is a need to be vigilant to combat any health disparities that emerge in the ESRD PPS.

b. CMS Activities To Advance Health Equity

The CMS Framework for Health Equity outlines a path to advance health equity that aims to support Quality Improvement Network Quality Improvement Organizations; federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other interested parties in activities to advance health equity.[181] The CMS Framework for Health Equity focuses on five core priority areas which inform our policies and programs: (1) Expand the collection, reporting, and analysis of standardized data; (2) Assess causes of disparities within CMS programs and address inequities in policies and operations to close gaps; (3) Build capacity of health care organizations and the workforce to reduce health and health care disparities; (4) Advance language access, health literacy, and the provision of culturally tailored services and, (5) Increase all forms of accessibility to health care services and coverage.[182] The CMS Quality Strategy [183] and Meaningful Measures Framework [184] also include elimination of disparities as central principles. CMS also requested information in the CY 2022 ESRD PPS proposed rule on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for ESRD facilities, providers, and patients (86 FR 36362 through 36367).

CMS's efforts aimed at advancing health equity to date have included providing transparency of health disparities, supporting health care providers and health officials with evidence-informed solutions to address social determinants of health and advance health equity, and reporting to providers on gaps in quality. Some of those efforts are:

- The *CMS Mapping Medicare Disparities Tool,* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[185]
- The *Rural-Urban Disparities in Health Care in Medicare Report,* which details rural-urban differences in health care experiences and clinical care.[186]
- *The CMS Innovation Center's Accountable Health Communities Model,* which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities,* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders reduce readmissions in diverse populations.[187]
- The *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams in order to enhance care for patients who are medically underserved with chronic kidney disease and are at risk of progression of disease or complications. The guide provides information about disparities in the care of patients with chronic kidney disease, presents potential actions that may improve care and suggests other available resources that may be used by primary care practice teams in caring for vulnerable patients.[188]

These efforts are informed by reports by the National Academies of Science, Engineering and Medicine and the Office of the Assistant Secretary for Planning and Evaluation, which have examined the influence of social risk factors on several of our programs.

2. Technical Expert Panel (TEP) Focused on Health Disparities Represented in the ESRD PPS

CMS continues to work with federal and private entities to better collect and leverage data on social determinants of health to improve our understanding of how these factors can be better measured in order to reduce health disparities and advance health equity. We continue to work to improve our understanding of this important issue and to identify policy solutions that achieve the goal of attaining health equity for all patients. One of the efforts demonstrating our ongoing commitment to uncover hidden disparities within the ESRD PPS includes the recently held TEP focused on improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services.

Over the last several years, CMS has been working towards a potential refinement of the ESRD PPS. This effort has included focused data analysis by CMS and included input of interested parties. Four contractor-led TEPs, each with a focus on different aspects of the ESRD PPS, have been convened. The specific objective for the latest TEP (December 2021) was to gather input from diverse interested parties on health disparities arising among patients who are historically medically underserved and are represented in the ESRD PPS patient populations. The TEP included 16 panelists representing ESRD facilities, nephrologists, patient advocates, and representatives from professional associations and industry groups. The contractor presented results of analysis of health disparities that can be measured by currently collected data. Panelists responded with their interpretations of these results and provided their insights about what they thought were hidden disparities not currently measured. Ideas and suggestions for potential changes to data collection for the ESRD PPS to better measure and potentially reduce health disparities were offered.

CMS is using this CY 2023 ESRD PPS proposed rule to issue an RFI on the topic of health equity issues within the ESRD PPS to obtain input from a broader spectrum of interested parties with a goal of improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services. The TEP did not provide formal recommendations, but provided discussion items and suggestions in a subsequent report. TEP presentation materials and summary

[181] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf.*

[182] Centers for Medicare & Medicaid Services Office of Minority Health. Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf.*

[183] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[184] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[185] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[186] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[187] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[188] CMS. Chronic Kidney Disease Disparities: Educational Guide for Primary Care. February 2020. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

reports can be found at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.*

a. TEP Discussion and Comments From Interested Parties

During the 2021 ESRD PPS TEP, panelists discussed various topics, including the types of direct patient care labor used in renal dialysis care, the case-mix payment adjustment model, subpopulations at risk of health disparities and for whom data are not currently available, and the special case of pediatric patients receiving renal dialysis services. The following is a synopsis of those discussion topics with the exception of pediatric renal dialysis services which is discussed in section II.E.4 of this proposed rule. For a more complete summary, please review the TEP Summary Report.[189]

(1) Direct Patient Care Labor Categories in Dialysis Care

CMS's contractor explained that direct patient care labor categories under the ESRD PPS include social workers, nutritionists, and other staff, but does not include nephrologists, as they are paid separately for their services to dialysis patients. The ESRD facility cost report includes lines for administrative and managerial staff. The base rate can be broken down into a direct patient care labor-related portion and a non-direct patient care labor-related portion, and that the direct patient care labor-related portion is multiplied by the facilities' CBSA wage index for the included job categories. In areas of the country with high wages, the wage index value usually exceeds one, increasing the labor-related portion of the base rate. The current wage index for the ESRD PPS is based on a pre-reclassified acute care hospital wage index and is not derived specifically from ESRD facility cost reports.[190] Panelists and other interested parties have commented that actual direct patient care labor costs associated with providing renal dialysis services are not currently being accurately captured and additional direct patient care labor categories should be explored.

(2) Case-Mix Model

The goal of case mix adjustment is to ensure payment accuracy, meaning payment for a treatment corresponds with expected resource use and cost for that treatment. As noted in the CY 2011 ESRD PPS final rule (75 FR 49034), resources required to furnish routine renal dialysis services such as staff and equipment time vary by patient. Because of the variation in resources required to furnish routine dialysis to individuals with varying patient characteristics, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate based on average resources. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite payment rate could create a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more resource-intensive patients, according to objective quantifiable criteria. To that end, the goal is to protect access to care for the least healthy and most costly beneficiaries and adequately compensate facilities with high proportion of those beneficiaries.

The ESRD PPS also includes a facility level adjustment designed to align ESRD facility resource use with payment. Facility level adjustments account for additional costs that facilities incur resulting from treatment volume, location, and proportion of high cost treatments (75 FR 49116 through 49127). At the facility level, panelists suggested that ESRD facilities located in areas with low physician to patient ratios and in disadvantaged areas also be considered.

Patient Characteristics and Comorbidities

Patient characteristics and comorbidities that best predicted variation in renal dialysis service costs were introduced in the CY 2011 ESRD PPS final rule (75 FR 49034) and revised in the CY 2016 PPS final rule (80 FR 68974 through 68979). The four case-mix adjusters are patient age, body surface area (BSA), low body mass index (BMI) and comorbidities (hereditary hemolytic or sickle cell anemia, myelodysplastic syndromes, gastrointestinal (GI) tract bleeding with hemorrhage, and pericarditis). Panelists noted that BSA and BMI are often correlated. Panelists stated there were other factors they believe were important to include in the case mix adjustment and suggested replacing the current low incidence comorbidities with others. One panelist suggested that upper GI bleeds be removed from the present list of comorbidities in favor of coronary artery disease history, diabetes history, and hypertension. Another panelist offered that respiratory failures should be considered, due to the frequency of this comorbidity they see in their practice. Finally, panelists strongly urged that CMS investigate the direct use of social determinants of health in the case-mix adjustment within the ESRD PPS.

(3) Subpopulations With Observable Disparities in Treatment or Outcomes Related to ESRD

Panelists noted the existence of patient sub-populations for whom data are not currently available that likely experience health disparities with regard to their treatment of ESRD. These include beneficiaries at ESRD facilities with low physician to patient ratios, as a lack of sufficient physician staffing could lead to poor access to care. Panelists also suggested that patients who are experiencing homelessness, undocumented, have limited English proficiency, and those that have mental health issues, should be considered subgroups at risk as well. They noted that many patients fit into more than one of these high-risk subgroups. Some panelists questioned whether the ADI was the best measure of neighborhood disadvantage as it does not consider availability of health resources within neighborhood groupings; however, they did not offer suggestions for any alternative measures.

(4) Payment Accuracy

Payment accuracy, for the purposes of the TEP discussion, was defined as how well ESRD PPS payments are aligned with observed costs for providing dialysis treatment. Panelists largely agreed that there was general alignment of costs and payments through the ESRD PPS, but they noted that there were patient groups and provider types for which payments were inadequate. The focus of these analyses was to explore potential disparities in payment accuracy among patient groups and provider types that might exacerbate health disparities. CMS's contractor presented information on payment accuracy across patient demographic subgroups (including age, sex, race/ethnicity), and facility types (including rural, low volume and geographically isolated facilities; and wage index and facility ownership type.) The panelists discussed at length the relationship between geographic isolation, patient access to care, and resulting costs. Panel members suggested that access to public transportation may be a relatively

[189] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[190] Pre-reclassified wage index in ESRD PPS means that wages for all hospital registered nurses are combined to obtain the CBSA-specific wages for RNs in ESRD facilities.

accurate marker of geographic isolation (defined as the distance between ESRD facilities) in urban areas. They also noted that geographic isolated communities were likely to have few primary care facilities and are also more likely to be ''food deserts.'' The panelists suggested that beneficiaries residing in these areas also experience difficulties in obtaining timely care for other medical conditions, such as diabetes, hypertension, and cardiovascular disease. They further noted that geographic isolation and difficulties in gaining access to care often results in a gaining access to care often results in a renal dialysis patient population with a greater burden of disease. Finally, panelists observed that patients in geographically isolated areas often turned to the renal dialysis facility for their unmet medical care needs. The panelists urged CMS to consider an upward payment adjustment for isolated facilities in areas where low income and low resources drive up the costs of providing care.

The panel focused much of their discussion around patient populations that faced special challenges in access to renal dialysis services and for whom the cost of care was likely higher, but who were not accounted for in current data collection activities under the ESRD PPS. The panel identified some of these patient subgroups to include: patients with housing insecurity as they are ineligible for both organ transplantation and home renal dialysis and thus dialyze in-center indefinitely; patients that are disabled or amputees who may require transfer assistance or extensive wound care; patients in hospice; patients who are not treatment compliant because of limited English proficiency, low health literacy, or behavior or mental health problems.

(5) Incorporation of ESRD PPS Payment Adjustments Based on Social Determinants of Health

Discussions during the December 2021 TEP discussion on SDOH were based on the definition of SDOH referring to non-biological factors that affect health status in a population.[191] The TEP members suggested making greater use of SDOH in the case-mix payment adjustment to help address additional costs associated with caring for patients with underlying social and economic risk factors (including, for example, housing insecurity, language barriers, lack of transportation, etc.) that make getting to and adhering to renal dialysis treatment more difficult and costlier for health care providers.

There are many factors that can contribute to increased costs. One panelist noted that their ESRD facility caseload included patients who were undocumented, experiencing homelessness, and had mental health issues, and these types of issues should be considered in payment models. Panelists strongly suggested that in order to better characterize the factors associated with increased treatment costs for these medically vulnerable and historically underserved patients who are at high-risk for adverse health outcomes, efforts should be made to standardize the collection of SDOH among patients enrolled in the ESRD PPS. They suggested several means of collecting this information including making more extensive use of the SDOH on the 2728 ESRD Medical Evidence Report Form (which is completed at the initiation of renal dialysis services); using SDOH screening tools and embedding them in patient enrollment materials; and using validated third party patient experience surveys. The panelists also suggested that this information be collected using Z codes in Medicare claims so that it could be updated on a regular basis, but cautioned that this would increase reporting burden on the facilities. The panelists also suggested that placing a modifier on claims to indicate the need for intensive resource utilization during renal dialysis services (for example, for amputees) may help better identify these costly patients. Another panelist suggested the focus should be on acting on the data already available instead of collecting more data.

Following the presentation on differences in treatment patterns among subgroups of the ESRD patient population, the panelist discussion focused on the following topics: home renal dialysis services, additional data elements that should be collected, potential payment changes to address disparities, and transportation. Panelists discussed potential reasons for differential use of home renal dialysis modalities and the need to track preventive care measures delivered through the more advanced stages of CKD. They also stated that better data on such patient characteristics as health literacy, English language proficiency, and transportation availability for treatment would help policymakers better understand treatment choices and treatment adherence.

Panelists also discussed treatment frequency and missed treatments in response to data presented by the contractor. While treatment frequencies did not vary significantly across patient race/ethnicity or proxies for income status, the following difference were found for the occurrence of missed treatments: American Indian/Alaska Native and Black/African American beneficiaries, beneficiaries with proxies (Medicare and Medicaid benefits, and ADI ranking) indicating lower socioeconomic status, and beneficiaries living in urban areas.[192] Some panelists suggested that missed treatments be incorporated into the case-mix adjustment; however, it was noted that the overall number of missed treatments is very small, across facility types. CMS data indicated on average, only one tenth of one percent of treatments are missed.

3. Request for Information on Advancing Health Equity Under the ESRD PPS

CMS plans to continue working with health care providers, the public, and other key interested parties on these important issues to identify policy solutions that achieve the goals of attaining health equity for all patients. Specifically, we are requesting comments on improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services. When responding, please note the question to which your comment is addressing.

Specifically, we are inviting public comment on the following:

- What kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity?
- Are there specific comorbidities that should be examined when calculating the case-mix adjustment that would help better represent the ESRD population and help address health disparities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such comorbidities.
- Are there specific subpopulations whose needs are not adequately accounted for by the current ESRD PPS payment policy and should be evaluated for potential health disparities?
- What are the challenges, and suggested ways to address, defining and collecting accurate and standardized, self-identified demographic information (including information on race and

[191] *https://academic.oup.com/ije/article/35/4/1111/686451.* A reference for social determinants of health can be found at the following website: *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[192] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2021.pdf;* slides 77, 78, 80, and 81.

ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would refine ESRD PPS payment policy.

++ What impact do SDOHs have on resource use and treatment costs for patients who are medically underserved?

++ Which SDOHs should data collection include?

++ How should data regarding SDOH be collected? How should such data be used in the ESRD PPS to help mitigate health disparities and promote health equity?

- How can CMS use existing data sources to better identify unmet needs among specific subpopulations that could result in health disparities?
- How can CMS revise case-mix categories in the ESRD PPS to better represent underserved populations?
- Are there actions CMS could potentially consider under the ESRD PPS to help prevent or mitigate potential bias in renal dialysis technologies, treatments, or clinical tools that rely on clinical algorithms? What are the relevant considerations for evaluating the effectiveness of such actions?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and we note that responses to the RFI should focus on how the suggestions could be applied to the ESRD PPS. Data to support any proposed revisions will be extremely important, so please include any data that supports your comments. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

4. Health Disparities Faced by Pediatric Patients Receiving Renal Dialysis Services Within the ESRD PPS

a. Background and Pediatric Dialysis Overview [193]

Compared to the Medicare dialysis adult population, the Medicare dialysis pediatric population is much smaller, comprising approximately 0.14 percent of the total ESRD patient population in 2019. Consequently, only 1.4 percent of ESRD facilities that furnish treatment in 2019 were pediatric facilities,[194] where ''pediatric facilities'' is defined as those providing at least 100 pediatric dialysis treatments in 2019. These facilities are mostly located in urban areas and typically based in a children's hospital or major medical center. Pediatric facilities are also either very small (furnishing less than 4,000 treatments per year) or very large (furnishing at least 10,000 treatments per year). Pediatric facilities also have higher direct patient care labor expenditures than adult facilities. The overall median person-hours of direct patient care labor per treatment in hospital-based facilities in 2019 was one hour more for pediatric facilities than for those serving adult Medicare dialysis patients. Registered nurses and licensed practical nurses contributed roughly double the person-hours toward a pediatric dialysis treatment compared to an adult dialysis treatment.

To examine pediatric dialysis treatment patterns during the TEP, the pediatric dialysis patient population was stratified into two age groups: patients younger than age 13 years old and those ages 13 to 17 years old. Pediatric patients younger than age 13 are more likely to dialyze using home peritoneal dialysis when compared to patients ages 13 to 17 and adults. Use of in-center hemodialysis increases as patients get older, and this modality was the most frequently used for teenagers (aged 13–17) and adults. Lastly, weekly treatment frequency tends to be very similar between the teenage and adult populations. Differences in treatment frequency mainly lie in the 99th percentile of pediatric patients younger than 13 years of age, who receive an average of five in-center hemodialysis sessions per week, a frequency rarely seen in the adult population.

b. TEP Discussion and Comments From Interested Parties

CMS has continued to hear concerns from organizations associated with pediatric dialysis about underpayment of pediatric renal dialysis services under the current ESRD PPS payment model. These organizations emphasize that pediatric renal dialysis services require significantly different staffing and supply needs from those of adults. Most of these organizations agree there is a need for more finely tuned cost data for pediatric dialysis. Many organizations support CMS efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. During the December 2020 TEP, panelists provided suggestions for the pediatric dialysis payment adjustment.[195] Those ideas were also discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36398; 36402 through 36404). Since pediatric dialysis patients represent the smallest sub-population in the Medicare ESRD PPS, CMS is using this RFI to ask interested parties to comment on health disparities that may exist for this population, and we are requesting input through this RFI on how changes to the ESRD PPS, including changes to data collection procedures, may help reduce any such disparities.

As noted earlier in this RFI, one of the efforts demonstrating CMS' ongoing commitment to closing the health equity gap includes the recently held TEP focused on health disparities represented in the ESRD PPS. See section II.E.2. of this proposed rule for more information about this TEP. The specific objective for this TEP (December 2021) was to gather input from a diverse group of interested parties on health disparities arising among patient groups represented in the ESRD PPS who are historically underserved. Issues regarding the pediatric population were discussed.

Comments from interested parties regarding the payment model for pediatric renal dialysis services have mostly focused on the high total cost of care for pediatric patients. Interested parties also have noted that although pediatric patients disproportionately receive treatment in hospital-based facilities, the hospital cost report (CMS Form 2552–10) does not distinguish between dialysis costs for pediatric and adult populations.

(1) Labor

Interested parties have commented during the TEPs and in response to prior rulemaking that the current collection of information does not account for the amount of staff time and the specialized staffing that is needed to provide care to this population. Many noted that costs unique to pediatric dialysis, such as child life specialists, developmental and behavioral psychologists, pediatric dieticians, and social workers, are not adequately captured in current cost reports or claims, and therefore are not

[193] ESRD TEP Summary Report of TEP held on December 10–11, 2020, p. 18–19. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[194] As per the 2020 TEP, 1.4 percent of all ESRD facilities were designated pediatrics, when defining pediatrics as >100 treatments/yr in 2019. See: *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf.*

[195] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

accounted for in pediatric adjustments (86 FR 36402). Commenters have explained that pediatric comorbidities require unique specialized care and that the cost of specialized direct patient care labor and supplies are not captured in the ESRD PPS.

(2) Case Mix

According to data provided by CMS's data contractor, compared to the national average, the ratio of payment relative to cost, standardized relative to the national average for pediatric dialysis treatment was the lowest among ESRD beneficiary age groups. Panelists asserted that the information that is currently collected in the Medicare cost report data do not enable CMS to estimate the true costs of treating pediatric patients. They also assert that key comorbidities for pediatric patient population are not included in case-mix adjustment. Furthermore, there are several challenges in the statistical analysis of pediatric dialysis costs. CMS adjusts the per treatment base rate for pediatric patients to account for patient age and treatment modality (42 CFR 413.235(b)). The small number of patients in this population reduces the precision of statistical models in estimating the true cost of treatment for pediatric dialysis. Another difficulty is disentangling composite rate costs for adult versus pediatric patients from the hospital-based facility cost report data, as these cost reports do not distinguish between adult and pediatric costs.[196]

Commenters have generally supported CMS' efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. In the CY 2022 ESRD PPS final rule (86 FR 61997), commenters suggested CMS make refinements to better capture costs by examining a breakdown of patient age groups, pediatric-specific dialysis supplies, additional overhead at hospital outpatient ESRD facilities, psychosocial support, specialized pharmacy needs and other costs unique to the pediatric population for home dialysis.

(3) Pediatric Comorbidities

One TEP panelist also noted that the comorbidities currently used in case-mix adjustment do not include those commonly seen in the pediatric population, such as seizure disorders, developmental delays, and congenital anomalies. The panelist and an organization representing pediatric nephrologists suggested other pediatric comorbidities should be considered when calculating the patient level case-mix adjuster. Those comorbidities are:

- Failure to thrive/feeding disorders—80 percent of children under 6 years of age require a G-tube and feeding pump for management of oral aversion or supplemental enteral nutrition to promote growth and ensure appropriate cognitive development;
- Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal);
- Congenital bladder/urinary tract anomalies;
- Non-kidney solid organ or stem cell transplant;
- Neurocognitive impairment;
- Global developmental delay;
- Cerebral palsy;
- Seizure disorder;
- Chronic lung disease (including dependency on continuous positive airway pressure machines and ventilators);
- Inability to ambulate or transfer;
- Vision impairment; and
- Feeding tube dependence.

During the discussion about the inability to transfer, inability to ambulate, and needs assistance with daily activities, one panelist noted some centers include these comorbidities for their patients, but others don't because they see them as age-related. For example, a 10-month old shouldn't be expected to ambulate. Therefore, the panel recommend that these conditions also have a designation as age-related which will probably result in more accurate and meaningful data for CMS.

5. Request for Information Regarding Dialysis for Pediatric ESRD Patients

CMS plans to continue working with health care providers, the public, and other key interested parties on these important issues to identify policy solutions that achieve the goals of attaining health equity for all patients. Specifically, we are requesting comments on improving CMS's ability to detect and reduce health disparities within the ESRD PPS payment program for pediatric patients receiving renal dialysis services. When responding, please note the question to which your comment is addressing.

Specifically, we are inviting public comment on the following:

- Please provide any information and supporting documentation about whether there are health disparities in this sub-population.
- How could refinements to the ESRD PPS payment policy mitigate health disparities in the pediatric population?
- Should a pediatric dialysis payment include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options (for example, age related or comorbidity related)?
- Are there specific comorbidities that should be examined when calculating the case-mix adjuster that would help better represent the pediatric ESRD population and help address health inequities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such conditions.
- Are there other direct patient care labor categories that should be considered when determining the cost to provide renal dialysis services to pediatric patients, and if so, which ones?
- How should CMS revise case-mix categories in the ESRD PPS to better represent the pediatric population?
- Are there SDOH that are specific to the pediatric ESRD population?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and note that responses to the RFI should focus on how the suggestions could be applied to the ESRD PPS. Data to support any proposed revisions will be extremely important, so please include any data that supports your comments. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

III. Calendar Year (CY) 2023 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

[196] ESRD TEP Summary Report of TEP held on December 10–11, 2020, p. 19. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

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 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 2023

1. CY 2023 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 productivity-adjusted 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.1.d of this proposed rule, the proposed CY 2023 ESRD PPS base rate is $264.09, which reflects the application of the proposed CY 2023 wage index budget-neutrality adjustment factor of 0.999992 and the CY 2023 proposed ESRDB market basket increase of 2.8 percent reduced by the productivity adjustment of 0.4 percentage point, that is, 2.4 percent. Accordingly, we are proposing a CY 2023 per treatment payment rate of $264.09 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index, as discussed in the next section of this proposed rule

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 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 reduced by the 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.1.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 2023 AKI dialysis payment rate of $264.09, adjusted by the ESRD facility's wage index. We are also proposing that the wage index floor increase discussed in section II.B.1.b.(2) of this proposed rule and the permanent 5-percent cap on wage index decreases discussed in section II.B.1.b.(3) of this proposed rule that we are proposing to apply under the ESRD PPS would apply in the same way to AKI dialysis payments to ESRD facilities.

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);
- CY 2020 ESRD PPS final rule (84 FR 60648);
- CY 2021 ESRD PPS final rule (85 FR 71398); and
- CY 2022 ESRD PPS final rule (86 FR 61874).

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

B. Flexibilities for the ESRD QIP in Response to the Public Health Emergency (PHE) Due to COVID–19

1. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the CY 2022 ESRD PPS final rule, we finalized a measure suppression policy for the duration of the COVID–19 Public Health Emergency (PHE) (86 FR 61910 through 61913). We stated that we had previously identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' control. We identified this need because we would like to ensure that facilities are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors, such as the COVID–19 PHE.

Specifically, we finalized a policy for the duration of the PHE for COVID–19 that enables us to suppress the use of measure data for scoring and payment adjustments if we determine that circumstances caused by the COVID–19 PHE have affected the measures and the resulting Total Performance Scores (TPSs) significantly. We also finalized the adoption of Measure Suppression Factors which will guide our determination of whether to suppress an ESRD QIP measure for one or more program years where the baseline or performance period of the measure overlaps with the PHE for COVID–19. The finalized Measure Suppression Factors are as follows:

- Measure Suppression Factor 1: Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Measure Suppression Factor 2: Clinical proximity of the measure's

focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE.

• Measure Suppression Factor 3: Rapid or unprecedented changes in:

++ clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

• Measure Suppression Factor 4: Significant national shortages or rapid or unprecedented changes in:

++ healthcare personnel;

++ medical supplies, equipment, or diagnostic tools or materials; or

++ patient case volumes or facility-level case mix.

We also stated that we would still provide confidential feedback reports to facilities on their measure rates on all measures to ensure that they are made aware of the changes in performance rates that we have observed. We also stated that we would publicly report suppressed measure data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19. We strongly believe that publicly reporting these data would balance our responsibility to provide transparency to consumers and uphold safety while ensuring that hospitals are not unfairly scored or penalized through payment under the ESRD QIP.

We are not proposing any changes to the measure suppression policy in this proposed rule.

2. Proposals To Suppress Six ESRD QIP Measures for PY 2023

a. Background

COVID–19 has had significant negative health effects—on individuals, communities, nations, and globally. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of early March 2022, over 78 million COVID–19 cases, 4.5 million new COVID–19 related hospitalizations, and 900,000 COVID–19 deaths have been reported in the U.S.[197] Provisional life expectancy data for CY 2020 showed that COVID–19 reduced life expectancy by 1.5 years overall, with the estimated impact disproportionately affecting minority communities.[198] According to this analysis, the estimated life expectancy reduction for Black and Latino populations is three times the estimate when comparing to the white population.[199] With a death toll surpassing that of the 1918 influenza pandemic, COVID–19 is the deadliest disease in American history.[200]

Additionally, impacts of the pandemic continued to accelerate in 2021 as compared with 2020. The Delta variant of COVID–19 (B.1.617.2) surfaced in the United States in early-to-mid 2021. Studies have shown that the Delta variant was up to 60 percent more transmissible than the previously dominant Alpha variant in 2020.[201] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to Center for Disease Control and Prevention (CDC) data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[202] With this increased transmissibility and morbidity associated with the Delta variant, we remain concerned about using measure data that is significantly impacted by COVID–19 for scoring and payment purposes for the PY 2023 program year.

In the CY 2022 ESRD PPS final rule, we finalized the suppression of the following measures for the PY 2022 program year:

- Standardized Hospitalization Ratio (SHR) clinical measure
- Standardized Readmission Ratio (SRR) clinical measure
- Long-Term Catheter Rate clinical measure
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure

Since the publication of the CY 2022 ESRD PPS final rule, we have conducted analyses on all ESRD QIP measures to determine whether and how COVID–19 has impacted the validity of the data used to calculate these measures for PY 2023. Our findings from these analyses are discussed below. Based on those analyses, we are proposing to suppress the following measures for PY 2023:

- SHR clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years);
- SRR clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years);
- Long-Term Catheter Rate clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years);
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:

++ healthcare personnel; or

++ patient case volumes or facility-level case mix);

- Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:

++ patient case volumes or facility-level case mix); and

- Kt/V Dialysis Adequacy clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could

[197] *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/index.html.*

[198] Arias E, Tejada-Vera B, Ahmad F, Kochanek KD. Provisional life expectancy estimates for 2020. Vital Statistics Rapid Release; no 15. Hyattsville, MD: National Center for Health Statistics. July 2021. DOI: *https://dx.doi.org/10.15620/cdc:107201.*

[199] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://www.pnas.org/content/118/5/e2014746118.*

[200] Branswell, Helen. Covid overtakes 1918 Spanish flu as deadliest disease in U.S. history. STAT. September 20, 2021. Available at: *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.*

[201] Allen H, Vusirikala A, Flannagan J, et al. Increased Household Transmission of COVID–19 cases associated with SARS–CoV–2 Variant of Concern B.1.617.2: a national case-control study. Public Health England. 2021.

[202] *https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.*

be significantly better or significantly worse compared to historical performance during the immediately preceding program years).

In the CY 2021 ESRD PPS final rule, we finalized that the mTPS for PY 2023 would be 57, and also finalized an associated payment reduction scale (85 FR 71471). However, as discussed below, we are proposing in this proposed rule to update the mTPS and payment reduction scale to reflect our proposal to suppress six measures for PY 2023, which is almost half of the current ESRD QIP measure set. We are also proposing to amend 413.178(a)(8) to state that the definition of the mTPS does not apply to PY 2023. The measures that we are proposing to score for PY 2023 are the Clinical Depression Screening and Follow-Up reporting measure, the Standardized Fistula Rate clinical measure, the Hypercalcemia clinical measure, the Standardized Transfusion Ratio (STrR) reporting measure, the Ultrafiltration Rate reporting measure, the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure, the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, and the NHSN Dialysis Event reporting measure. The proposed re-calculated mTPS for PY 2023 would be 80. If one or more of our measure suppression proposals is not finalized, then we would to revise the mTPS for PY 2023 so that it includes all measures that we finalize for scoring for PY 2023. We are also proposing to codify these proposals in our regulations by adding a new 413.178(i), which specifies that we will calculate a measure rate for each of the suppressed measures, but will not score facility performance on those suppressed measures or include them in the facility's TPS for PY 2023. Proposed 413.178(i) would also define the mTPS for PY 2023 as the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on the measures described in proposed 413.178(i)(2). As discussed in section IV.C of this proposed rule, we are also proposing to calculate the performance standards for PY 2023 using CY 2019 data, and are proposing to revise our regulations at 413.178(d)(2) to reflect this proposal.

We continue to be concerned about the impact of the COVID–19 PHE, but we are encouraged by the rollout of COVID–19 vaccinations and treatment for those diagnosed with COVID–19 and we believe that facilities are better prepared to treat patients with COVID–19. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. Additionally, we want to emphasize the long-term importance of incentivizing quality care tied to payment. The ESRD QIP is an example of our long-standing effort to link payments to healthcare quality in the dialysis facility setting.[203]

We understand that the COVID–19 PHE is ongoing and unpredictable in nature, however, we believe that 2022 has a more promising outlook in the fight against COVID–19. As we enter the third year of the pandemic, healthcare providers have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations. In 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations,[204] including the availability and use of vaccination for young children ages 5 to 11, who were not eligible for vaccination for the majority of 2021 and for whom only 32 percent had received at least one dose as of February 23, 2022.[205] [206] Additionally, FDA has expanded availability of at-home COVID–19 treatment, having issued the first emergency use authorizations (EUAs) for two oral antiviral drugs for the treatment of COVID–19 in December 2021.[207] [208] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[209] N–95 masks,[210] and increase COVID–19 testing in schools,[211] providing more treatment and testing to the American people. Therefore, our goal is to continue resuming the use of all measure data for scoring and payment adjustment purposes beginning with the PY 2024 ESRD QIP. That is, for PY 2024, for each facility, we would plan to calculate measure scores for all of the measures in the ESRD QIP measure set for which the facility reports the minimum number of cases. We would then calculate a TPS for each eligible facility and use the established methodology to determine whether the facility would receive a payment reduction for the given payment year. We understand that the PHE for COVID–19 is ongoing and unpredictable in nature, and we would continue to assess the impact of the PHE on measure data used for the ESRD QIP.

b. Proposal To Suppress the SHR Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the SHR clinical measure for PY 2023 program year under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on SHR clinical measure performance (86 FR 61914 through 61915). The SHR clinical measure is an all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is

[203] CMS has also partnered with the CDC in a joint Call to Action on safety, which is focused on our core goal to keep patients safe. Fleisher et al. (2022). *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

[204] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron.*

[205] KFF, Update on COVID–19 Vaccination of 5–11 Year Olds in the U.S., *https://www.kff.org/coronavirus-covid-19/issue-brief/update-on-covid-19-vaccination-of-5-11-year-olds-in-the-u-s/.*

[206] *https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/.*

[207] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID–19. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19.*

[208] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID–19 in Certain Adults. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,progression%20to%20severe%20COVID%2D19%2C.*

[209] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID-19 Tests to Americans for Free. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/.*

[210] Miller, Z. 2021. *The Washington Post.* Biden to give away 400 million N95 masks starting next week Available at: *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-7915-11ec-9dce-7313579de434_story.html.*

[211] The White House. (2022). FACT SHEET: Biden-Harris Administration Increases COVID-19 Testing in Schools to Keep Students Safe and Schools Open. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/.*

defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the facility's patients and the national norm for facilities. This measure is calculated as a ratio but can also be expressed as a rate. The intent of the SHR clinical measure is to improve health care delivery and care coordination to help reduce unplanned hospitalization among ESRD patients.

Based on our analysis of Medicare dialysis patient data from January 2021 through September 2021, we found that hospitalizations involving patients diagnosed with COVID–19 resulted in higher mortality rates, higher rates of discharge to hospice or skilled nursing facilities, and lower rates of discharge to home than hospitalizations involving patients who were not diagnosed with COVID–19. Specifically, the hospitalization rate for Medicare dialysis patients diagnosed with COVID–19 was up to three times greater than the hospitalization rate during the same period for Medicare dialysis patients who were not diagnosed with COVID–19, which is much greater than the relative risk of hospitalization for any other comorbidity. Similar to our analysis in the CY 2022 ESRD PPS final rule (86 FR 61915), we believe that this indicates that COVID–19 has had a significant impact on the hospitalization rate for dialysis patients. Because COVID–19 Medicare dialysis patients are at significantly greater risk of hospitalization, and the SHR clinical measure was not developed to account for the impact of COVID–19 on this patient population, we continue to be concerned about the effects of the observed COVID–19 hospitalizations on the SHR clinical measure. We also note that the waves of the Delta and Omicron variants during 2021 affected different regions of the country at different rates depending on factors like time of year, geographic density, state and local policies, and health care system capacity.[212] [213] Because of the increased hospitalization risk associated with COVID–19 and the Medicare dialysis patient population, we are concerned that these regional differences in COVID–19 rates have led to distorted hospitalization rates such that we could not reliably make national, side-by-side comparisons of facility performance on the SHR clinical measure.

We also analyzed data from January 2020 through September 2021, which indicates that hospitalization [214] and mortality rates [215] were 6 times higher in the ESRD population. Although our measure suppression analysis focuses on CY 2020 and CY 2021 data and we only have partial CY 2021 data available at this time, we believe that the remaining 2021 data will continue to show similar trends. Not only are there effects on patients diagnosed with COVID–19, but our data indicates that the presence of the virus continued to strongly affect hospital admission patterns of dialysis patients through September 2021 and we believe that similar effects will be seen in October through December 2021 data.

Following emergence of the Delta variant in 2021, we have also observed disproportionate increases in COVID–19 cases and related deaths among ESRD beneficiaries. Similarly, emergence of the Omicron variant in December 2021 was followed by another mortality spike. Because the COVID–19 pandemic generally, and the Delta and Omicron waves specifically, swept through geographic regions of the country unevenly, we are additionally concerned that facilities in different regions of the country would have been affected differently throughout 2021, thereby skewing measure performance and affecting national comparability. Based on the impact of COVID–19 on SHR results, including the continued deviation in measurement, we believe that the SHR clinical measure meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believe that the resulting performance measurement on the SHR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

We believe that the SHR clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the COVID–19 PHE would continue affecting measure performance on the current SHR clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. However, we are proposing to continue to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We also propose to continue providing confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We intend to publicly report PY 2023 data where feasible and appropriately caveated.

In the CY 2022 ESRD PPS final rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SHR clinical measure (86 FR 61915). We discuss our technical specifications update to the SHR clinical measure to risk-adjust for patients with a history of COVID–19 in section IV.B.3 of this proposed rule.

We welcome public comment on our proposal to suppress the SHR clinical measure for PY 2023.

c. Proposal To Suppress the SRR Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the SRR clinical measure for the PY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on SRR clinical measure performance (86 FR 61915 through 61916). The SRR clinical measure assesses the number of readmission events for the patients at a facility, relative to the number of readmission events that would be expected based on overall national rates and the characteristics of the patients at that facility as well as the number of discharges. The intent of the SRR clinical measure is to improve care coordination between ESRD facilities and hospitals to improve communication prior to and post discharge.

Based on our analysis, we have found that index discharge hospitalizations involving dialysis patients diagnosed

[212] Cuadros DF, Miller FD, Awad S, Coule P, MacKinnon NJ. Analysis of Vaccination Rates and New COVID–19 Infections by US County, July–August 2021. *JAMA Netw Open.* 2022;5(2):e2147915. doi:10.1001/jamanetworkopen.2021.47915

[213] Iuliano AD, Brunkard JM, Boehmer TK, et al. Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS–CoV–2 High Transmission Periods—United States, December 2020–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:146–152. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e4external* icon.

[214] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-services-through-2021-08-21.pdf.*

[215] Turgutalp, K., Ozturk, S., Arici, M. et al. Determinants of mortality in a large group of hemodialysis patients hospitalized for COVID–19. BMC Nephrol 22, 29 (2021). *https://doi.org/10.1186/s12882-021-02233-0.*

with COVID–19 resulted in lower readmissions and higher mortality rates within the first 7 days in 2021. We used index hospitalizations occurring from January 2020 through August 2021 to identify eligible index hospitalizations and unplanned hospital readmissions. Focusing on the partial year data for 2021, we found that total hospital readmissions, average number of index discharges, and average number of readmissions were lower than in full-year data for 2018 and 2019. We note that our analysis of 2020 data revealed that overall average readmission rates were similar to pre-COVID years, but that hospitalization in COVID–19 patients resulted in very different outcomes, with increased in-hospital and early post-discharge death and increased discharge to subacute rehabilitation facilities. Although our measure suppression focuses on CY 2021 data and we only have partial CY 2021 data available at this time, we believe that the remaining 2021 data will continue to show similar trends. Our analysis of partial year data for 2021 found that average re-admission rates were slightly lower overall compared to 2018 and 2019. Although we are still analyzing the data for 2021, we believe that similar to 2020, these competing outcomes of index hospitalization continue to have a significant effect on readmission rates, affecting interpretation of hospitalization outcomes between COVID-associated and non-COVID events. Based on this demonstrated association between recent COVID–19 infection and altered patterns of hospitalization and readmission compared to those for non-infected ESRD patients, we remain concerned about the effects of these observations on the calculations for the SRR clinical measure. We note that our preliminary analyses only looked at data through August 2021, which would not fully capture readmission data from the Delta or Omicron surges of the COVID–19 PHE. Based on the impact of COVID–19 on SRR results, including the continued deviation in measurement, we believe that the SRR clinical measure meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believe that the resulting performance measurement on the SRR clinical measure would not be sufficiently reliable or valid for use in the PY 2023 ESRD QIP for scoring and payment adjustment purposes.

We believe that the SRR clinical measure is an important part of the ESRD QIP Program measure set. However, we remain concerned that the PHE for the COVID–19 pandemic continues to affect measure performance on the current SRR clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. Additionally, we propose continuing to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We intend to publicly report PY 2023 data where feasible and appropriately caveated.

In the CY 2022 ESRD PPS final rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SRR clinical measure (86 FR 61916). We discuss our technical specifications update to the SRR clinical measure to risk-adjust for patients with a history of COVID–19 in section IV.B.3 of this proposed rule.

We welcome public comment on our proposal to suppress the SRR clinical measure for PY 2023.

d. Proposal To Suppress the Long-Term Catheter Rate Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the Long-Term Catheter Rate clinical measure for PY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on the Long-Term Catheter Rate clinical measure for PY 2022 (86 FR 61917).

In the CY 2018 ESRD PPS final rule, we finalized the inclusion of the Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure in the ESRD QIP measure set beginning with the PY 2021 program (82 FR 50778). The Long-Term Catheter Rate clinical measure is defined as the percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access. The measure is based on vascular access data reported in CMS' ESRD Quality Reporting System (EQRS) (previously, CROWNWeb) and excludes patient-months where a patient has a catheter in place and has a limited life expectancy. The measure evaluates the vascular access type used to deliver hemodialysis. The intent of the Long-Term Catheter Rate clinical measure is to improve health care delivery and patient safety.

Our analysis based on the available data indicated that long-term catheter use rates increased significantly during the COVID–19 PHE. Average long-term catheter rates were averaging around 12 percent during the period CY 2017 through early CY 2020. As we noted in the CY 2022 ESRD PPS final rule, we observed an increase in long-term catheter rates during the pandemic in CY 2020, with rates reaching a peak of 14.7 percent in June 2020 and declining slightly to 14.3 percent in July and August 2020 (86 FR 61917). After remaining around 12 percent for 3 consecutive years, in the CY 2022 ESRD PPS final rule we stated that we view a sudden 2 percent increase in average long-term catheter rates as a significant deviation compared to historical performance during immediately preceding years (86 FR 61917). Since then, we have observed a steady rate increase throughout CY 2021, with unadjusted catheter rates reaching a peak of 17.9 percent in September 2021. By contrast, the unadjusted catheter rates in CY 2019 peaked at 12 percent. We believe that the steep increase in catheter rates during CY 2021 indicates a significant deviation in performance on the Long-Term Catheter Rate clinical measure. We are concerned that the COVID–19 PHE continues to impact the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 exposure and increased associated health risks, and that these contributed to the significant increase in long-term catheter use rates.

We believe that the Long-Term Catheter Rate clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the PHE for COVID–19 affected measure performance on the current Long-Term Catheter Rate clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. Additionally, participating facilities

would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2023 data where feasible and appropriately caveated.

We welcome public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2023.

e. Proposal To Suppress the ICH CAHPS Clinical Measure for PY 2023

We are proposing to suppress the ICH CAHPS measure for the PY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years and Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in healthcare personnel and patient case mix. We would calculate facilities' ICH CAHPS measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Participating facilities would continue to report the measure data to CMS so that we can monitor the effect of the circumstances on quality measurement and consider appropriate policies in the future. We would continue to provide confidential feedback reports to facilities as part of program activities to allow facilities to track the changes in performance rates that we observe. We also intend to publicly report CY 2021 measure rate data where feasible and appropriately caveated. As noted in section IV.B.1 of this proposed rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding the quality of care and safety for consumers.

In the CY 2022 ESRD PPS final rule (86 FR 61916 through 61917), we finalized our proposal to suppress the ICH CAHPS clinical measure for the PY 2022 program year under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. Based on our analysis of CY 2020 ICH CAHPS data, we finalized our proposal to suppress the ICH CAHPS clinical measure for PY 2022 because we found a significant decrease in response scores as compared to previous years. Our most recent analysis that includes Spring 2021 ICH CAHPS data shows a continued deviation in ICH CAHPS scores.

The ICH CAHPS clinical measure is scored based on three composite measures and three global ratings.[216] Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always'' to assess the patient's experience of care at a facility. Facility performance on each composite measure is determined by the percent of patients who choose ''top-box'' responses (that is, most positive or ''Always'') to the ICH CAHPS survey questions in each domain. The ICH CAHPS survey is administered twice yearly, once in the spring and once in the fall.

Our most recent data indicates that, although the number of participating facilities that submitted data has increased from pre-COVID–19 levels, the number of completed interviews has dropped dramatically. For example, in Spring and Fall 2019, facilities reported 98,868 and 96,255 completed interviews, respectively. By contrast, in Spring and Fall 2021, only 82,987 and 61,930 completed interviews were submitted, respectively. In other words, although a larger number of facilities are submitting ICH CAHPS data, fewer patients within each of those facilities are completing interviews and, as a result, a fewer number of facilities are meeting the survey minimum to be included in the measure for ESRD QIP scoring purposes because of the continuing impact of the PHE.

We believe that these data may also reflect a rapid and unprecedented change in healthcare personnel, as staffing shortages may have had an impact on some of the top box rating scores.

During the course of the PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in healthcare settings.[217] This healthcare personnel shortage worsened in 2021, with hospitals across the United States reporting 296,466 days of critical staffing shortages, an increase of 86 percent from the 159,320 days of critical staffing shortages hospitals reported in 2020.[218] Although there is no specific data regarding the healthcare personnel shortages in facilities, reports indicate that facilities have experienced similar staffing shortages.[219] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[220] [221]

Additionally, reports of staff shortages have varied widely geographically. In January 2021, half of the hospitals in New Mexico and over 40 percent of the hospitals in Vermont, Rhode Island, West Virginia, and Arizona reported staffing shortages.[222] Conversely, in that same week, less than 10 percent of hospitals in Washington, DC, Connecticut, Alaska, Illinois, New York, Maine, Montana, Idaho, Texas, South Dakota, and Utah reported staffing shortages. We believe that these staffing shortages reported by hospitals are

[216] Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf.*

[217] Health Affairs, *COVID–19's Impact on Nursing Shortages, The Rise of Travel Nurses, and Price Gouging* (Jan. 28, 2022), *https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/.*

[218] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh.*

[219] National Kidney Foundation, *COVID–19 and its Impact on Kidney Patients Utilizing U.S. Dialysis Centers* (Jan. 18, 2022), *https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers.* See also, Becker's Hospital Review, *Supply shortages disrupt dialysis care in Texas* (Jan. 28, 2022), *https://www.beckeshospitalreview.com/supply-chain/supply-shortages-disrupt-dialysis-care-in-texas.html.* WBIW, *Pandemic causing supply shortages for dialysis patients, staffing shortage for providers* (Feb. 22, 2022), *https://www.wibw.com/2022/02/22/pandemic-causing-supply-shortages-dialysis-patients-staffing-shortage-providers/.* Spectrum News, Worker shortage sends dialysis patients scrambling for treatment (October 4, 2021), *https://spectrumlocalnews.com/nys/hudson-valley/news/2021/10/01/worker-shortage-sends-dialysis-patients-scrambling-for-treatment.*

[220] Kriti Prasad, Colleen McLoughlin, Martin Stillman, Sara Poplau, Elizabeth Goelz, Sam Taylor, Nancy Nankivil, Roger Brown, Mark Linzer, Kyra Cappelucci, Michael Barbouche, Christine A. Sinsky. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID–19 pandemic: A national cross-sectional survey study. EClinicalMedicine, Volume 35. 2021. 100879. ISSN 2589–5370. *https://doi.org/10.1016/j.eclinm.2021.100879.*

[221] Vizheh, M., Qorbani, M., Arzaghi, S.M. *et al.* The mental health of healthcare workers in the COVID–19 pandemic: A systematic review. *J Diabetes Metab Disord* 19, 1967–1978 (2020). *https://doi.org/10.1007/s40200-020-00643-9.*

[222] U.S. News, States With the Biggest Hospital Staffing Shortages (Jan. 13, 2022), *https://www.usnews.com/news/health-news/articles/2022-01-13/states-with-the-biggest-hospital-staffing-shortages* (citing data from the HHS, CDC, and Assistant Secretary for Preparedness and Response Community Profile Report, updated frequently and available here: *https://healthdata.gov/Health/COVID-19-Community-Profile-Report/gqxm-d9w9*).

similar to those experienced by facilities, and that the shortages experienced by ESRD facilities may be even worse due to the highly specialized nature of nephrology staff. Given the wide variance in reported staffing shortages, and the impact staffing shortages may have on ICH CAHPS top box rating scores, we believe our proposal to suppress the ICH CAHPS measure fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating facilities.

Due to the emergence of COVID–19 variants, such as the Delta and Omicron variants that have arisen from COVID–19 and our belief that facilities have experienced worsening staffing shortages in Q3 and Q4 2021,[223] [224] we anticipate that Fall 2021 data would continue to demonstrate a deviation in national performance such that scoring this measure would not allow us to reliably make national, side-by-side comparisons of facility performance on the ICH CAHPS measure. We believe that suppressing this measure for the PY 2023 would address concerns about the potential unintended consequences of penalizing facilities for deviations in measure performance resulting from the impact of the COVID–19 PHE.

Therefore, we are proposing to suppress the ICH CAHPS measure for the PY 2023 ESRD QIP under Measure Suppression Factors 1 and 4.

We welcome public comment on this proposal.

f. Proposal To Suppress the PPPW Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the PPPW clinical measure for PY 2023 under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years, as well as under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes or facility-level case mix.

The PPPW clinical measure is a process measure that assesses the percentage of patients at each 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. Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, we adopted the PPPW clinical measure in the CY 2019 ESRD PPS final rule to encourage facilities to coordinate care with transplant centers to waitlist patients (83 FR 57003 through 57008).

In the CY 2022 ESRD PPS final rule (86 FR 61914), several commenters recommended that CMS suppress the PPPW clinical measure, noting that the COVID–19 PHE had a significant negative impact on transplant surgeries, referrals, and waitlists, as well as other related areas. A few commenters also noted that waitlist additions significantly decreased during the COVID–19 PHE. At the time, we responded that our analysis of the relevant data available at the time of the proposed rule indicated temporal declines in waitlist removal among prevalent patients and similarly a decline in waitlisting and transplants in incident ESRD patients in March 2020 through May 2020 compared to prior years. We also observed that trends generally returned to normal starting in June and July 2020 and reflected data similar to prior years. However, we also indicated that we would continue to monitor and review the data and would consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

After reviewing data for the PPPW clinical measure for CY 2021, we believe that circumstances caused by the COVID–19 PHE have affected our ability to make reliable national, side-by-side comparisons of facility performance on the PPPW measure. Recent analyses indicate that measure performance has declined over the course of the COVID–19 PHE. Although the initial disruptions in care and associated effects on the PPPW measure at the beginning of the COVID–19 PHE initially stabilized, we have since observed a continuous decrease in the levels of PPPW clinical measure performance. We believe this decrease is indicative overall of the significant impact of the COVID–19 PHE on the measure. For example, in January 2019, the monthly PPPW rate was 19 percent. By contrast, the monthly PPPW rate for December 2021 was 16.9 percent, which we believe reflects a significant deviation in national performance on the measure. We have also observed that a greater number of facilities would receive lower scores in PY 2023 as compared to PY 2022, reflecting poorer performance overall on the measure. For example, our simulations indicate that the percentage of facilities receiving scores lower than 5 (out of 10; a higher score reflects better performance) have increased at almost every data point. Notably, the percentage of facilities estimated to receive a score of 0, 1, or 2 increased the most between the PY 2022 and PY 2023, indicating that facilities are more likely to receive a lower score in PY 2023. Moreover, the percentage of facilities receiving scores higher than 5 on the PPPW clinical measure in PY 2023 have decreased at each data point. Given the correlation between decreasing scores and the pandemic's impact on care delivery and patient ability to access the appropriate level of care in light of COVID–19 precautions, we believe that the COVID–19 PHE continues to have a significant impact on the PPPW clinical measure during CY 2021.

Our analysis of the available data indicates that the COVID–19 PHE has had significant effects on the PPPW clinical measure and would result in significant deviation in national performance on the measure during the COVID–19 PHE. Not only are there effects on patients diagnosed with COVID–19, but the presence of the virus strongly affected treatment patterns of dialysis patients in CY 2020 and continued to do so in CY 2021, and we are concerned that similar effects would be seen in the balance of the 2021 calendar year as the PHE had continued. Because the Delta variant and the Omicron variant surged through geographic regions of the country unevenly, we are concerned that facilities in different regions of the country would have been affected differently throughout the 2021 year, thereby skewing measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. Given the limitations of the data available to us for CY 2021, we believe the resulting performance measurement on the PPPW clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

We believe that the PPPW clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the ongoing COVID–19 PHE has affected measure performance

[223] Bloomberg, U.S. Hospital Staff Shortages Hit Most in a Year on Covid Surge, *https://www.bloomberg.com/news/articles/2022-01-05/one-in-five-u-s-hospitals-face-staffing-shortages-most-in-year* (citing HHS data).

[224] Fresenius Medical Care Press Release, Statement regarding COVID–19 related supply and staff shortages. Available at: *https://fmcna.com/company/covid-19-resource-center/*.

on the current PPPW clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we would continue to collect the measure's data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2023 data where feasible and appropriately caveated.

We are currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on the PPPW clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the PPPW clinical measure as additional data become available. As an alternative, we considered whether we could exclude patients with a diagnosis of COVID–19 from the PPPW clinical measure cohort, but we determined suppression would provide additional time and months of data for us to more thoroughly evaluate a broader range of alternatives. We want to ensure that the measure reflects care provided to ESRD patients and we are concerned that excluding otherwise eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across facilities over time.

We welcome public comment on our proposal to suppress the PPPW clinical measure for PY 2023.

g. Proposal To Suppress the Kt/V Dialysis Adequacy Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023 program year under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the overall impact of the COVID–19 PHE on ESRD quality measure performance (86 FR 61910 through 61913).

The Kt/V Dialysis Adequacy clinical measure is the 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. The Kt/V Dialysis Adequacy clinical measure is defined as a measure of dialysis sufficiency where *K* is dialyzer clearance, *t* is dialysis time, and *V* is total body water volume. The measure evaluates the success of achieving the delivered dialysis dose. The intent of the Kt/V measure is to improve health care delivery by providing facilities with evidence-based parameters for optimizing ESRD patient outcomes over time.

In the CY 2022 ESRD PPS final rule (86 FR 61910), several commenters recommended that CMS suppress the Kt/V Dialysis Adequacy clinical measure, noting that the COVID–19 PHE had a significant impact on catheter rates, which has a corresponding impact on the Kt/V measure, as patients with catheters will have lower Kt/V rates. One commenter also noted the Kt/V Dialysis Adequacy clinical measure should be suppressed under Suppression Factor 1, due to significant deviation in national measure performance. At the time, we responded there was not sufficient data to determine whether suppression was appropriate for the Kt/V Dialysis Adequacy clinical measure. Although performance on the Kt/V Dialysis Adequacy clinical measure deviated temporarily, our analysis indicated that Kt/V rates stabilized shortly thereafter and reflected measure performance similar to prior years. Based on our analysis at the time, Kt/V rates in CY 2020 were similar to rates in CY 2019 until April where they dropped by an average of 0.4 percent. However, beginning in June 2020, Kt/V rates were the same as or higher than national average rates in March 2020.

After reviewing data for the Kt/V Dialysis Adequacy clinical measure for CY 2020 and CY 2021, we believe that circumstances caused by the COVID–19 PHE have affected the measure and the resulting TPS. Although the initial disruptions of care at the beginning of the COVID–19 PHE, associated with multiple transient changes to factors that contribute to dialysis adequacy (Kt/V), were temporary, we have observed continued deviations in Kt/V clinical measure performance over the past 2 years and we believe that this is indicative of the significant impact of the COVID–19 PHE on the measure. Notably, delays in hemodialysis treatment, due to COVID–19 infection or logistical challenges with care delivery, exacerbated ESRD sequelae including hyperkalemia, uremic encephalopathy, and fluid volume overload.[225] The confluence of these factors likely contributed to declines in Kt/V clinical measure performance.

Our simulations comparing PY 2022 scoring distributions with estimated PY 2023 scoring distributions show that the percentage of facilities receiving scores less than 7 (out of 10; a higher score reflects better performance) have increased at almost every data point, whereas the percentage of facilities receiving scores higher than 7 have decreased at almost every data point. The percentage of facilities receiving a score of score of 0, 1, 2, 3, or 4 increased the most between the 2 years, indicating that facilities are more likely to receive a lower score in PY 2023. Given the correlation between decreasing scores and the pandemic's impact on care delivery and patient ability to access the appropriate level of care in light of COVID–19 precautions,[226] we believe that the COVID–19 PHE continued to have a significant impact on the Kt/V clinical measure during CY 2021.

Our analysis of the available data indicates that the COVID–19 PHE has had significant effects on the Kt/V Dialysis Adequacy clinical measure for ESRD patients and would result in significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly worse as compared to historical performance during the immediately preceding program years. Because the Delta variant and Omicron variant surged through geographic regions of the country unevenly, we are concerned that facilities in different regions of the country have been affected differently throughout the 2021 calendar year, resulting in skewing of measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. We note that our scoring simulations indicate that a high percentage of facilities would receive a score of zero for PY 2023. Given the limitation of the data available to us for CY 2021, we believe the resulting performance measurement of the Kt/V Dialysis Adequacy clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for

[225] Connerney, M., Sattar, Y., Rauf, H., Mamtani, S., Ullah, W., Michaelson, N., Dhamrah, U., Lal, N., Latchana, S., & Stern, A.S. (2021). Delayed hemodialysis in COVID–19: Case series with literature review. *Clinical nephrology. Case studies, 9*, 26–32. *https://doi.org/10.5414/CNCS110240.*

[226] National Kidney Foundation, *COVID–19 and its Impact on Kidney Patients Utilizing U.S. Dialysis Centers* (Jan. 18, 2022), *https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers.*

scoring and payment adjustment purposes.

We believe that the Kt/V Dialysis Adequacy clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the ongoing COVID–19 PHE has affected measure performance on the current Kt/V Dialysis Adequacy clinical measure such that we would not be able to score facilities fairly or equitably on it. Moreover, we would continue to collect the measure's data from participating facilities so that we could monitor the effect of the COVID–19 PHE circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2023 data where feasible and appropriately caveated.

We are currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on the Kt/V Dialysis Adequacy clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the Kt/V Dialysis Adequacy clinical measure as additional data become available.

We welcome public comment on our proposal to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023.

3. Technical Measure Specification Updates To Include a Covariate Adjustment for COVID–19 for the SHR and SRR Measures Beginning With PY 2025

In the CY 2013 ESRD PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the ESRD QIP (77 FR 67475 through 67477).

As we continue to evaluate the effects of COVID–19 on the ESRD QIP measure set, we have observed both short-term effects on both hospital admissions and readmissions. In addition, for some patients COVID–19 continues to have lasting effects, including but not limited to fatigue, cough, palpitations, and others potentially related to organ damage, post viral syndrome, and post-critical care syndrome.[227] These clinical conditions could affect a patient's risk of complications following an index admission or readmission and, as a result, impact a facility's performance on the SHR clinical measure or the SRR clinical measure. In order to account for case mix among facilities, the current risk adjustment approach for these measures include covariates for clinical comorbidities that are relevant and have relationships with the outcome, for example patient history of diabetes or obesity. Therefore, in order to adequately account for patient case mix, we are further modifying the technical measure specifications for the SHR and SRR measures to include a covariate adjustment for patient history of COVID–19. We believe these changes are technical in nature because they do not substantively change the measures themselves and, therefore, are not required to be implemented through rulemaking.

This inclusion of the covariate adjustment for patient history of COVID–19 would be effective beginning with the PY 2025 program year for the SHR clinical measure and the SRR clinical measure, and we would also apply this adjustment for purposes of calculating the performance standards for that program year. As discussed in section IV.E.1.b, we are proposing to convert the STrR reporting measure to a clinical measure beginning with PY 2025. We are also considering whether it would be appropriate to add a covariate adjustment for patient history of COVID–19 to the STrR clinical measure, beginning with PY 2025, and will announce that technical update, if appropriate, at a later date.

For more information on the application of covariate adjustments, including the technical updates we are announcing in this proposed rule, please see the Technical Specifications for ESRD QIP Measures (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications*) and the CMS ESRD Measures Manual (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/06_MeasuringQuality*).

C. Proposed Updates to the Performance Standards Applicable to the PY 2023 Clinical Measures

Our current policy is to automatically adopt a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year (84 FR 60728). Under this policy, CY 2021 is currently the performance period and CY 2020 is the baseline period for the PY 2023 ESRD QIP. However, under the nationwide ECE that we granted in response to the COVID–19 PHE, first and second quarter data for CY 2020 are excluded from scoring for purposes of the ESRD QIP (85 FR 54829 through 54830). Accordingly, in the CY 2022 ESRD PPS final rule (86 FR 61922 through 61923), for PY 2024, we finalized calculating performance standards using CY 2019 data due to concerns about using partial year data (86 FR 61922 through 61923). Similarly, we are concerned that it would be difficult to assess performance standards for PY 2023 based on partial year data. Our preliminary analysis indicates that the effect of the excluded data could create inflated performance standards for PY 2023 and we would potentially be required to use these for future payment years due to the requirement that the prior year's standard cannot be higher than the current year's standard. This may skew achievement and improvement thresholds for facilities and therefore may result in performance standards that do not accurately reflect levels of achievement and improvement.

Our current policy substitutes the performance standard, achievement threshold, and/or benchmark for a measure for a performance year if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than the numerical values for that measure in the previous year of the ESRD QIP (82 FR 50764). We adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years and therefore, adopted flexibility to substitute the performance standard, achievement threshold, and benchmark in appropriate cases.

Although the lower performance standards would be substituted with those from the prior year, the higher performance standards would be used to set performance standards for certain measures, even though they would be based on partial year data. We continue to be concerned that this may create performance standards for certain measures that would be difficult for facilities to attain with 12 months of data.

Therefore, we are proposing to calculate the performance standards for PY 2023 using CY 2019 data, which are the most recently available full calendar year of data we can use to calculate those standards. Due to the impact of CY 2020 data that are excluded from the ESRD QIP for scoring purposes, we believe that using CY 2019 data for performance standard setting purposes is appropriate. We are also proposing to amend 413.178(d)(2) to reflect both our

[227] Raveendran, A.V., Jayadevan, R. and Sashidharan, S., *Long COVID: An overview.* Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056514/.* Accessed on December 15, 2021.

proposed updates applicable to the PY 2023 performance standards, as well as our previously finalized update to the PY 2024 performance standards.

We welcome public comments on this proposal.

D. Technical Updates to the SRR and SHR Clinical Measures Beginning With the PY 2024 ESRD QIP

In the CY 2017 ESRD PPS final rule, we adopted the SHR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77906 through 77911). The SHR clinical measure is a National Quality Forum (NQF)-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the facility's patients and the national mean for facilities. In the CY 2015 ESRD PPS final rule, we adopted the SRR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (79 FR 66174 through 66182). The standardized readmission ratio is defined as the ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day hospital readmissions. Both the SHR clinical measure and the SRR clinical measure are calculated as a ratio, but can also be expressed as a rate.

Hospitalization and readmission rates vary across facilities even after adjustment for patient characteristics, suggesting that hospitalizations and readmissions might be influenced by facility practices. Both an adjusted facility-level standardized hospitalization ratio and an adjusted facility-level standardized readmissions ratio, accounting for differences in patients' characteristics, play an important role in identifying potential quality issues, and help facilities provide cost-effective quality health care to help reduce admissions or readmissions to the hospital for dialysis patients as well as limit escalating medical costs. We have weighted scoring of the SHR clinical measure and the SRR clinical measure to reflect the importance of the measures on the quality of patient care. In the CY 2019 ESRD PPS final rule, the SHR clinical measure and the SRR clinical measure each accounted for 14 percent of the TPS (83 FR 56992). In CY 2019, with average weights of more than 15 percent (after reweighting of missing measures), the SHR clinical measure and the SRR clinical measure were the two measures with the largest weight in calculating the TPS for each facility.

In the CY 2013 ESRD PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the ESRD QIP (77 FR 67475 through 67477). We are updating the technical specifications to revise how we express the results of the SHR clinical measure and the SRR clinical measure so that those results are expressed as a Risk-Standardized Hospitalization Rate (RSHR) and a Risk-Standardized Readmission Rate (RSRR), respectively. Stakeholders have previously expressed concern that the SHR clinical measure and the SRR clinical measure are difficult to interpret and track facility performance over time when expressed as ratios, and have recommended expressing those ratios as rates when scoring. Although there are widespread national improvements in hospitalization rates and readmission rates, individual facilities may not their own improvement reflected if their measure results are reflected as ratios because SHR and SRR measures effectively standardize the ratios to 1.0 each calendar year and all facilities' ratios are calculated using national-level performance in each calendar year. Another concern stakeholders have raised is that the ratios are difficult to understand and to determine how to use these ratios for quality improvement efforts.

In light of these concerns, we are updating the technical specifications to change the scoring methodology for the SRR clinical measure and the SHR clinical measure such that a facility's results are expressed as a rate in the performance period that is compared directly to its rate in the baseline period. In response to public comments indicating a perception that overall facility performance on ESRD QIP measures was recently improving as payment reductions were increasing, we assessed trends in facility performance through 2019 to examine facility performance on the SHR clinical measure and the SRR clinical measure over time. We also calculated the RSHR and the RSRR. We calculated the RSHR by multiplying SHR by the national observed hospitalization rate (per patient-year at risk) in the calendar year. Similarly, we multiplied the SRR by the national observed readmission rate (per index discharge) in the calendar year to determine the RSRR. Both ESRD QIP and Dialysis Facility Reports (DFR) data were used in these analyses. Data from ESRD QIP were available from CYs 2018 to 2019 for the SRR clinical measure and from CYs 2015 to 2019 for the SHR clinical measure. Additionally, we used data from the publicly available DFRs from CYs 2010 to 2018 for the SHR clinical measure and from CYs 2014 to 2018 for the SRR clinical measure to compare to the ESRD QIP calculations.

We believe these changes are technical in nature because they do not substantively change the measures themselves and, therefore, are not required to be implemented through rulemaking. Our analysis found that expressing the measure performance as a rate instead of a ratio would communicate the same information in a clearer way. After the SHR clinical measure and the SRR clinical measure were added to the ESRD QIP measure set, that SHR and SRR distributions were similar from year to year. Median SHR has consistently remained below 1.0, while median SRR has remained around 1.0 each year. RSHR and RSRR have remained stable since then as well. These trends show that as ESRD QIP payment reductions were increasing from PY 2018 to PY 2020 (corresponding to CY 2016 to CY 2018 facility performance for most measures), we do not find evidence of overall declines in risk-adjusted hospitalization and readmission rates. Furthermore, in recent years, the national readmission or hospitalization rates have been relatively stable or slightly increasing. Therefore, revising how we express SHR or SRR measure results to be expressed as RSHR or RSRR, respectively, each year would not result in higher ESRD QIP scores.

Our analysis found that expressing the SHR clinical measure and SRR clinical measure results as rates would reflect the same level of measure performance as expressing those results as ratios, and we believe that expressing the measure results rates would help providers and patients better understand a facility's performance on the measures, and would be more intuitive for a facility to track its performance from year to year.

Further, this technical update would also more closely align with the measure result calculation methodology for the ESRD QIP with that used in the Dialysis Facility Compare Star Ratings Program. For star ratings calculations, an adjustment factor is applied for the standardized ratio measures, accounting for differences in population event rates between the baseline period and evaluation period data, so that an adjusted evaluation period ratio (a proxy for rate converted from ratio) value reflects the same value it would

have in the baseline period.[228] We provide the currently finalized performance standards for the PY 2024 SHR and SRR clinical measures in Table 16, and the revised PY 2024 performances standards for the updated SHR and SRR clinical measures in Table 17.

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TABLE 16: Current Performance Standards for the PY 2024 ESRD QIP SHR and SRR 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)
Standardized Readmission Ratio	1.268*	0.998*	0.629*
Standardized Hospitalization Ratio	1.230	0.971	0.691
*Values are also the final performance standards for those measures for PY 2023. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2024 because they are higher standards than the PY 2024 numerical values for those measures.			

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

TABLE 17: Numerical Values for the Performance Standards for the Updated PY 2024 ESRD QIP SHR and SRR Clinical Measures, Expressed as Rates, 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)
Standardized Readmission Ratio[a]	34.27	26.97	17.02
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR, STrR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

We welcome public comments on this technical update.

E. Proposed Updates to Requirements Beginning With the PY 2025 ESRD QIP

1. PY 2025 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 2025 ESRD QIP measure set would include the same 14 measures as the PY 2024 ESRD QIP measure set (85 FR 71465 through 71466). In section IV.E.1.a of this proposed rule, we are also proposing to adopt a COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) reporting measure beginning in PY 2025. In section IV.E.1.b of this proposed rule, we are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, and in section IV.E.1.c, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025. These measures are described in Table 18 in this proposed rule. For the most recent information on each measure's technical specifications for PY 2025, we refer readers to the CMS ESRD Measures Manual for the 2022 Performance Period.[229]

[228] The University of Michigan Kidney Epidemiology and Cost Center. (2018). Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release. Available at: *https://dialysisdata.org/sites/default/files/content/Methodology/Updated_DFC_Star_Rating_Methodology_for_October_2018_Release.pdf.*

[229] *https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf.*

TABLE 18: Proposed PY 2025 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.
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 End Stage Renal Disease Quality Reporting System (EQRS) one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure Number of patient-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 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 performed and documented by an eligible professional.
N/A	COVID-19 Healthcare Personnel (HCP) Vaccination, a reporting measure**** Percentage of HCP who receive a complete COVID-19 vaccination course.

* We are updating the SHR clinical measure and the SRR clinical measure to be expressed as risk-standardized rates beginning in PY 2024, as discussed in section IV.D of this proposed rule.

**We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule.

***We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.

****We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

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We discuss our proposal to adopt the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) reporting measure, our proposal to convert the

STrR reporting measure to a clinical measure, and our proposal to convert the Hypercalcemia clinical measure to a reporting measure in the following sections.

a. Proposal To Adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Reporting Measure Beginning With the PY 2025 ESRD QIP

(1) Background

On January 31, 2020, the Secretary declared a PHE for the U.S. in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[230] COVID–19 is a contagious respiratory infection [231] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[232]

COVID–19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of March 16, 2022, over 79 million COVID–19 cases, over 4.5 million new COVID–19 related hospitalizations, and almost 965,000 COVID–19 deaths have been reported in the U.S.[233]

The CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[234] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[235] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between healthcare personnel (HCP) and patients, or from patient to patient, given the close contact that may occur during the provision of care.[236] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[237]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[238] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[239] Subsequently, FDA issued EUAs for additional COVID–19 vaccines [240] and, after a rigorous review process, granted approval to two vaccines.[241]

We believe that it is important to incentivize and track HCP vaccination for COVID–19 in facilities through quality measurement in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to continue serving their communities throughout the PHE and beyond. We recognize the importance of COVID–19 vaccination, and have finalized proposals to include a COVID–19 HCP vaccination measure in quality reporting programs for other care settings, such as the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (86 FR 45438 through 45446), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (86 FR 42385 through 42396), and the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489).

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death themselves as a result of contracting COVID–19, and transmitting COVID–19 to their families, friends, and the general public. For further information regarding the importance of vaccination among HCP, we refer readers to the ''Omnibus COVID–19 Health Care Staff Vaccination,'' an interim final rule with comment that was issued on November, 11, 2021, requiring COVID–19 vaccination of eligible staff at health care facilities that participate in the Medicare and Medicaid programs (such as facilities participating in ESRD QIP) (86 FR 61556 through 615560). We believe that facilities should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[242] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[243] and we believe that HCP COVID–19 vaccination in facilities could similarly increase uptake among that patient population. We also believe

[230] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[231] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[232] Ibid.

[233] *https://covid.cdc.gov/covid-data-tracker#datatracker-home.*

[234] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[235] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[236] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[237] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859. Available at: *https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm.*

[238] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[239] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download.* (as reissued on September 22, 2021).

[240] U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download* (as reissued on August 12, 2021); U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download* (as reissued on June 10, 2021).

[241] FDA Approves First COVID–19 Vaccine, Available at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.* Spikevax and Moderna COVID–19 Vaccine, Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine.*

[242] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[243] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

that publishing the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19 such as dialysis patients, as they choose facilities from which to seek treatment. Patients undergoing hemodialysis face greater risk for adverse health outcomes if they contract COVID–19 and during the Delta and Omicron surges of 2021, increases in case rates were directly proportionate to vaccination rates at the county level across the United States [244] [245] Under CMS' Meaningful Measures Framework, the COVID–19 HCP Vaccination measure would address the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 HCP Vaccination measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-long-term care facilities such as ESRD facilities.

The denominator is the number of HCP eligible to work in the ESRD facility for at least one day during the reporting period (as described in section IV.E.1.a.(5)) excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[246] [247]

The numerator is the cumulative number of HCP eligible to work in the ESRD facility for at least one day during the reporting period (as described in section IV.E.1.a.(5)) and who received a complete vaccination course against COVID–19 using an FDA-authorized or approved vaccine for COVID–19. A complete vaccination course is defined under the specific FDA EUA or approval and may require multiple doses or regular revaccination.[248] [249] Vaccination coverage is defined, for purposes of this measure, as the percentage of HCP eligible to work at the facility for at least 1 day who received a complete vaccination course against COVID–19. The specifications for this measure are available at *https://www.cdc.gov/nhsn/nqf/index.html.*

(3) Review by the Measure Applications Partnership

The COVID–19 HCP Vaccination measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[250] When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed measures on the MUC List including the COVID–19 HCP Vaccination measure. The MAP Hospital Workgroup recognized that the proposed measure represents a promising effort to advance measurement for an ongoing and evolving national pandemic and that it would bring value to the ESRD QIP measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[251] The MAP Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP, and providing feedback to facilities, would allow facilities to benchmark coverage rates and improve coverage in their facility. The MAP Hospital Workgroup further noted that reducing rates of COVID–19 in HCP may reduce transmission among a patient population that is highly susceptible to illness and disease, and also reduce instances of staff shortages due to illness.[252]

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[253] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[254] Subsequently, the MAP Coordinating Committee reviewed the COVID–19 HCP Vaccination measure and the preliminary recommendation of the Hospital Workgroup, and decided to recommend conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications were further refined.[255] In its final report, the MAP further noted that the measure would add value to the ESRD QIP measure set by providing visibility into an important intervention to limit COVID–19 infections in HCP and the ESRD patients for whom they provide care.[256]

In response to the MAP's request that CMS return with the measure once the specifications are further refined, we met with the MAP Coordinating Committee accompanied by the CDC on March 15, 2021 to address vaccine availability, the alignment of the COVID–19 HCP Vaccination measure as closely as possible with the Influenza HCP vaccination measure (NQF #0431) specifications, and the definition of HCP used in the measure. At this meeting, with the CDC, we also presented preliminary findings from ongoing testing of the numerator of COVID–19 HCP Vaccination measure, which showed that the numerator data should be feasible and reliable.[257] Testing of the numerator, the number of HCP vaccinated, involved a comparison of vaccination data reported to the CDC by long-term care facilities (LTCFs) through the CDC's National Healthcare Safety Network (NHSN) with data reported to the CDC through the federal pharmacy partnership program for delivering vaccination to LTC facilities. These two data collection systems are independent but show high correlation. In initial analyses of the first month of

[244] Cuadros DF, Miller FD, Awad S, Coule P, MacKinnon NJ. Analysis of Vaccination Rates and New COVID–19 Infections by US County, July–August 2021. *JAMA Netw Open.* 2022;5(2):e2147915. doi:10.1001/jamanetworkopen.2021.47915.

[245] Iuliano AD, Brunkard JM, Boehmer TK, et al. Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS–CoV–2 High Transmission Periods—United States, December 2020–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:146–152. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e4external* icon.

[246] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed January 7, 2022 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[247] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. (2021) Accessed March 29, 2022 at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[248] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[249] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. (2021) Accessed March 29, 2022 at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[250] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

[251] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[252] Ibid.

[253] Ibid.

[254] Ibid.

[255] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[256] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[257] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

vaccination from December 2020 to January 2021, the number of HCP vaccinated in approximately 1,200 facilities was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[258] Because of the high correlation across a large number of facilities, including ESRD facilities, and the high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe these data indicate the measure is feasible and reliable for use in the ESRD QIP.

(4) NQF Endorsement

Section 1881(h)(2)(B)(i) of the Act states that subject to subparagraph (ii), any measure specified by the Secretary for the ESRD QIP must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Under section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed COVID–19 HCP Vaccination measure is not NQF endorsed. The CDC, in collaboration with CMS, submitted the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore the exception in section 1881(h)(2)(B)(ii) of the Act applies. We believe it is important to propose this measure as quickly as feasible to address the ongoing COVID–19 pandemic and to prepare for potential future waves of COVID–19 variants, including the potential continued negative impact of COVID–19 infection on the ESRD patient population as well as HCP staffing shortages due to COVID–19 infection among staff.

(5) Data Collection, Submission, and Reporting

We are proposing quarterly reporting deadlines for the ESRD QIP and a 12-month performance period. Facilities would report the measure through the NHSN web-based surveillance system.[259] Facilities currently use the NHSN web-based system to report two ESRD QIP measures, the NHSN Bloodstream Infection (BSI) clinical measure and the NHSN Dialysis Event reporting measure.

To report this measure, we propose that facilities would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ESRD QIP requirements. While it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that facilities would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a facility's healthcare personnel while balancing the costs of reporting. If a facility submits more than one week of data in a month, the most recent week's data would be used to calculate the measure, as we believe the most recent week's data would provide the most currently available information. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we propose that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each facility, which would be calculated by taking the average of the data from the three weekly rates submitted by the facility for that quarter. We would publicly report the most recent quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IV.E.1.a.(2) of this proposed rule, facilities would report the number of HCP eligible to have worked at the facility during the self-selected week that the facility reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

We welcome public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among HCP, to the ESRD QIP measure set beginning with PY 2025.

b. Proposed Updates to the Standardized Transfusion Ratio (STrR) Reporting Measure Beginning With PY 2025

Under section 1881(h)(2)(A)(iv)(I) of the Act, the ESRD QIP has a statutory requirement to include an anemia management measure in the Program's measure set, and the STrR reporting measure currently satisfies that statutory requirement. In the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197), we finalized the adoption of the STrR clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP. The NQF endorsed a revised version of the STrR clinical measure in 2016, and in the CY 2018 ESRD PPS final rule (82 FR 50771 through 50774), we adopted the revised version of the STrR clinical measure beginning with the PY 2021 ESRD QIP.

Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the validity of the modified STrR measure (NQF #2979) finalized for adoption beginning with PY 2021 (83 FR 56993 through 56994). Commenters specifically stated that due to the new level of coding specificity required under the ICD–10–CM/PCS coding system, many hospitals were no longer accurately coding blood transfusions. The commenters further stated that because the STrR clinical measure was calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals had negatively affected the validity of the STrR measure (83 FR 56993 through 56994).

In the CY 2020 ESRD PPS final rule (84 FR 60720 through 60723), we finalized our proposal to convert the STrR clinical measure to a reporting measure while we examined these validity concerns. Accordingly, we finalized that, beginning with PY 2022, we would score the STrR measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. We stated our desire to ensure that the Program's scoring methodology results in fair and reliable STrR measure scores because those scores are linked to facilities' TPS and possible payment reductions. We also stated our belief that the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that facilities are not adversely affected during our

[258] Ibid.

[259] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on January 7, 2022.

continued examination of the measure was to convert the STrR clinical measure to a reporting measure.

In November 2020, the NQF renewed its endorsement of the STrR clinical measure after performing an ad hoc review based on updates we made to the measure's specifications to address coding and validity concerns. Under the revised STrR clinical measure, inpatient transfusion events are identified using a broader definition that includes revenue center codes only, ICD procedure codes (alone or with revenue codes), or value codes alone or in combination. We believe that these updates would result in identification of a greater number of inpatient transfusion events compared to the previously implemented STrR clinical measure. In addition, the revised STrR clinical measure would effectively mitigate a provider coding bias that was exacerbated by the conversion from ICD–9 to ICD–10 code sets in late CY 2015.

In light of the NQF's endorsement and adoption of the updated STrR clinical measure specifications, we are proposing to convert the STrR reporting measure to the revised STrR clinical measure using the revised specifications that were endorsed by the NQF. We believe that previous validity concerns have been adequately examined and addressed, that facilities have had sufficient time to gain experience with the updated measure specifications through reporting the updated measure for Dialysis Facility Compare, and converting back to the STrR clinical measure would be consistent with our intent to more closely align with NQF measure specifications where feasible (84 FR 60724).

In addition to our proposal to convert the STrR reporting measure to a clinical measure, we are also proposing to update the scoring methodology for the STrR clinical measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR clinical measure based on the actual clinical values reported by the facility, rather than the successful reporting of the data. We are also proposing to express the proposed STrR clinical measure as a rate, rather than as a ratio. We believe that converting the STrR clinical measure to be expressed as a rate would help providers and patients better understand a facility's performance on the measures, and would be more intuitive for a facility to track its performance from year to year. To assess the impact of expressing STrR measure results as rates, we multiplied the facility level STrR by the national average transfusion rate. Our analysis found that the difference between the distribution of STrR measure scores expressed as a ratio and expressed as a rate was generally less than 1 percent. Therefore, we believe that expressing STrR measure results as a rate would not result in different ESRD QIP scores. This approach would also align with our technical updates to the SHR clinical measure and the SRR clinical measure, as discussed in section IV.D of this proposed rule.

We welcome public comment on our proposals.

c. Proposal To Convert the Hypercalcemia Clinical Measure to a Reporting Measure Beginning With PY 2025

Section 1881(h)(2)(A)(iv)(II) of the Act states that the measures specified for the ESRD QIP must include, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Many studies have associated disorders of mineral metabolism with mortality, fractures, cardiovascular disease, and other morbidities. Therefore, in the CY 2014 ESRD PPS final rule (78 FR 72200 through 72203), we adopted the Hypercalcemia clinical measure as part of the ESRD QIP measure set, which we believed would encourage adequate management of bone mineral metabolism and disease in patients with ESRD.

In recent years, we have received numerous public comments expressing concern about the role and weight of the Hypercalcemia clinical measure in the ESRD QIP. Many stakeholders have indicated that they believe the measure is topped out, pointing out that the NQF has placed the measure in Reserve Status because of high facility performance and minimal room for improvement. As a result, the ability to distinguish meaningful differences in performance between facilities is substantially reduced because small random variations in measure rates can result in different scores. Others have expressed concern about whether the Hypercalcemia clinical measure is the best measure in the bone mineral metabolism domain to impact patient outcomes.

Taking into account these persistent concerns expressed by stakeholders, we are currently examining the continued viability of the Hypercalcemia clinical measure as part of the ESRD QIP measure set. We also acknowledge that there may be other measures of bone mineral metabolism that are more informative or effective than the Hypercalcemia clinical measure, such as the serum phosphorus measure.[260]

Although recent annual measure analyses have indicated that the Hypercalcemia clinical measure may not be fully topped out based on the statistical criteria that we adopted in the CY 2015 ESRD PPS final rule (79 FR 66174), they also indicate that the measure is very close to being topped out. Under our previously adopted methodology, a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (TCV) of less than or equal to 0.1. To determine whether a clinical measure is topped out, we initially focus on the top distribution of facility performance on each measure and note if their 75th and 90th percentiles are statistically indistinguishable. Then, to ensure that we properly account for the entire distribution of scores, we analyze the truncated coefficient of variation (TCV) for the measure. Based on a 2017 analysis using CY 2015 CROWNWeb measure data, the Hypercalcemia clinical measure did not meet both conditions. Although the TCV was less than 1 percent, the difference between the 75th percentile (0.91) was statistically distinguishable from the 90th percentile (0.32). However, given that the TCV was so low and was calculated by removing the lower and upper 5th percentiles, we believe it is possible that certain outliers in the 90th percentile could have skewed the statistically distinguishable part of the topped out analysis. In other words, although the Hypercalcemia clinical measure is not considered topped out based on our previously adopted methodology, we believe that it is very close to being topped out based on the available data and are concerned that small differences in measure performance may disproportionately impact a facility's score on the measure.

Therefore, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025 while we explore possible replacement measures that would be more clinically meaningful for purposes of quality improvement. We are also proposing to update the scoring methodology so that facilities that meet previously finalized minimum data and eligibility requirements would receive a

[260] CMS ESRD QIP PY 2020 Final Measure Technical Specifications. Accessed May 18, 2022 at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2020-Technical-Specification.pdf.*

score on the Hypercalcemia reporting measure based on the successful reporting of the data, rather than the actual clinical values reported by the facility. Facilities would be scored using the following equation, beginning in PY 2025:

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

If finalized, the Hypercalcemia reporting measure would be in our proposed Reporting Measure Domain, which we discuss in section IV.E.2.

We welcome public comments on our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning in PY 2025.

2. Proposed Revisions To Measure Domains and to the Domain and Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2025 ESRD QIP

In the CY 2019 ESRD PPS final rule (83 FR 56991 through 56992), we finalized revisions to the ESRD QIP measure domains. Specifically, we eliminated the Reporting Domain and reorganized the Clinical Domain into three distinct domains: Patient & Family Engagement Domain, Care Coordination Domain, and Clinical Care Domain. We stated that adopting these topics as separate domains would result in a measure set that is more closely aligned with the priority areas in the Meaningful Measures Framework.[261] We also continued use of the Patient Safety Domain, which aligns with the Meaningful Measures Framework priority to make care safer by reducing harm caused in the delivery of care. In that rule, we finalized our proposal to eliminate the Reporting Measure Domain from the ESRD QIP scoring methodology, beginning in PY 2021, because there would no longer be any measures in that domain as a result of our finalized proposals to reassign the Ultrafiltration Rate and Clinical Depression Screening and Follow-Up Reporting measures to the Clinical Care Measure Domain and the Care Coordination Measure Domain, respectively (83 FR 56991 through 56997).

In the CY 2019 ESRD PPS final rule, we also stated our intent to reassess how the finalized ESRD QIP measure domains and domain weights affect TPSs awarded under the Program in the future (83 FR 56995). We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden. We also consider criteria previously used to determine appropriate domain and measures weights, including: (1) The number of measures and measure topics in a proposed domain; (2) how much experience facilities have had with the measures and measure topics in a proposed domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214) (that is, the Meaningful Measures Framework priorities, which includes our preferred emphasis on patient outcomes).

Currently, ESRD QIP measures are weighted and distributed across four measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, and Safety. Based on changes to the measure set since PY 2021, including adoption of the Medication Reconciliation (MedRec) reporting measure, the PPPW clinical measure, and the measure-related proposals in this proposed rule, we have reassessed the impact of the ESRD QIP measure domains and domain weights on TPSs, and we believe it is necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, especially on patient clinical outcomes. Therefore, we are proposing to create a new Reporting Measure Domain which would include the four current reporting measures in the ESRD QIP measure set, as well as the proposed COVID–19 HCP Vaccination reporting measure and the proposed Hypercalcemia reporting measure. We note that we are proposing to convert the STrR reporting measure to a clinical measure, as discussed in section IV.E.1.b of this proposed rule, and as a result, we are proposing that the proposed STrR clinical measure would be placed in the Clinical Care Measure Domain.

We are also proposing to update the domain weights and individual measure weights in the Care Coordination Domain, Clinical Care Domain, and Safety Domain accordingly to accommodate the new Reporting Measure Domain and individual reporting measures therein. As the ESRD QIP measure set has evolved over the years, we believe this would help to address concerns regarding the impact of individual measure performance on a facility's TPS, while also further incentivizing improvement on clinical measures. For a comparison of current and proposed measure domains and weighting, please see Table 19 and Table 20.

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[261] CMS website, Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

TABLE 19: Current ESRD QIP Measure Domains and Weights

Measure/Measure Topics By Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	4.00
Clinical Depression and Follow-Up reporting measure	2.00
Clinical Care Measure Domain	**40.00**
Kt/V Dialysis Adequacy Comprehensive Measure	9.00
Vascular Access Type Measure Topic	12.00
STrR measure	10.00
Hypercalcemia measure	3.00
Ultrafiltration Rate measure	6.00
Safety Measure Domain	**15.00**
NHSN BSI clinical measure	8.00
MedRec measure	4.00
NHSN Dialysis Event reporting measure	3.00

TABLE 20: Proposed ESRD QIP Measure Domains and Weights

Measure/Measure Topics By Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	6.00
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure*	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Clinical Depression and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure**	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure***	1.67

* We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule.
**We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.
***We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

We welcome public comment on our proposal to create a new Reporting Domain and to update the existing domains and measure weights used to calculate the TPS, beginning with PY 2025.

3. Estimated Performance Standards for the PY 2025 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer

readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2022 ESRD PPS final rule (86 FR 61927), we set the performance period for the PY 2025 ESRD QIP as CY 2023 and the baseline period as CY 2021. We note that, for the six measures we are proposing to suppress in section IV.B.2 of this proposed rule, we would continue to use CY 2019 data as the baseline period for those measures. We believe that this is consistent with our established policy to use the prior year's numerical values for the performance standards if the most recent full CY's final numerical values are worse. For the measures that we are proposing to suppress for PY 2023, this would result in no measure data that could be used for CY 2021 baseline period. Therefore, this would result in worse performance standards for those suppressed measures in PY 2025. In this proposed rule, we are estimating the performance standards for the PY 2025 clinical measures in Table 21 using data from CY 2019, which is the most recent data available. We intend to update these standards for the non-suppressed measures, using CY 2021 data, in the CY 2023 ESRD PPS final rule.

TABLE 21: Estimated Performance Standards for the PY 2025 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	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Hypercalcemia**	1.54%	0.49%	0.00%
Risk-Standardized Readmission Rate[a]	34.27	26.97	17.02
NHSN BSI	1.193	0.516	0
Risk-Standardized Hospitalization Rate[b]	187.80	148.33	105.54
Risk-Standardized Transfusion Rate[b]	47.45	27.01	10.56
PPPW	8.12%*	16.73%*	33.90%*
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	62.22%	76.57%
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%

*Values are the same final performance standards for those measures for PY 2024. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2025 because they are higher standards than the PY 2025 numerical values for those measures.

**We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule. If this proposal is finalized, we would update the table accordingly in the final rule.

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 Organ Procurement and Transplantation Network (OPTN).

In addition, we summarize in Table 22 existing requirements for successful reporting on reporting measures in the PY 2025 ESRD QIP.

TABLE 22: Requirements for Successful Reporting on the PY 2025 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every hemodialysis (HD) Kt/V session during the week of the monthly Kt/V draw, and the number of sessions of dialysis is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of blood urea nitrogen (BUN) Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
STrR*		At least 10 patient-years at risk during the performance period.
Hypercalcemia**	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 HCP Vaccination***	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2.

*We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule. If finalized, we would update this table in the final rule.
**We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.
***We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

4. Eligibility Requirements for the PY 2025 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 23. We are not proposing any changes to these eligibility requirements for the PY 2025 ESRD QIP in this proposed rule.

TABLE 23: 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	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)**	10 patient-years at risk	N/A	N/A
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 HCP Vaccination (Reporting)***	11 qualifying healthcare personnel	N/A	N/A

* We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.
**We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule. If finalized, we would update this table in the final rule.
***We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

5. Payment Reduction Scale for the PY 2025 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a 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 42 CFR 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 42 CFR 413.177 of our regulations, also implements 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 mTPS (76 FR 634 through 635).

For PY 2025, based on available data, a facility must meet or exceed a mTPS of 55 in order to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2019 instead of the PY 2025 baseline period (CY 2021) because CY 2021 data are not yet available.

We refer readers to Table 19 of this proposed rule 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 55 would receive a payment reduction based on the TPS ranges indicated in Table 24.

TABLE 24: Estimated Payment Reduction Scale for PY 2025 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-55	0%
54-45	0.5%
44-35	1.0%
34-25	1.5%
24-0	2.0%

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We intend to update the mTPS for PY 2025, as well as the payment reduction ranges for that payment year, in the CY 2023 ESRD PPS final rule.

F. Updates for the PY 2026 ESRD QIP

1. Continuing Measures for the PY 2026 ESRD QIP

Under our previously adopted policy, the PY 2025 ESRD QIP measure set would also be used for PY 2026. We are not proposing to adopt any new measures beginning with the PY 2026 ESRD QIP.

2. Performance Period for the PY 2026 ESRD QIP

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2024 as the performance period and CY 2022 as the baseline period for the PY 2026 ESRD QIP.

We are not proposing any changes to this policy.

3. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 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 define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2026 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 2021 data. We intend to publish these numerical values, using CY 2021 data, in the CY 2023 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2026 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 would continue use of these performance standards in PY 2026. In sections IV.E.1.c and IV.E.1.a of this proposed rule, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure and to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025, and would include these in the performance standards for reporting measures in the PY 2026 ESRD QIP if this proposal is finalized.

4. Scoring the PY 2026 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 42 CFR 413.178(e). In section IV.E.1.b of this proposed rule,

we are proposing to update our scoring methodology beginning with PY 2025.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at 42 CFR 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 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). In the CY 2021 ESRD PPS final rule, we finalized our updated scoring methodology for the Ultrafiltration Rate reporting measure (85 FR 71468 through 71470). In section IV.E.1.c of this proposed rule, we are proposing to update our scoring methodology as part of our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning with PY 2025. We are also proposing to adopt a scoring methodology as part of our proposal to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025, as discussed in section IV.E.1.a of this proposed rule.

5. Weighting the Measure Domains and the TPS for PY 2026

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).

In section IV.E.2 of this proposed rule, we are proposing the addition of a new Reporting Measure Domain, and we are proposing new weights for the four existing measure domains, beginning in PY 2025. If finalized, we would update the measure weights and domains and the TPS for PY 2026 accordingly in the final rule.

G. Requests for Information (RFI) on Topics Relevant to ESRD QIP

1. Request for Information on Quality Indicators for Home Dialysis Patients

In this proposed rule, we are seeking public comments on potential indicators of quality for patients who receive dialysis at home in order to support the use of home dialysis for ESRD patients where it is appropriate. While home-based dialysis may not meet the needs of every patient, home dialysis has clear benefits for those who are suitable candidates. Often, it may be more convenient for many ESRD patients, and survivability rates for home dialysis are comparable to those of transplant recipients and in-center hemodialysis.[262]

There are two general types of dialysis: hemodialysis (HD), in which an artificial filter outside of the body is used to clean the blood; and peritoneal dialysis (PD), in which the patient's peritoneum, covering the abdominal organs, is used as the dialysis membrane. HD is conducted at an ESRD facility, usually three times a week, or at a patient's home, often at a greater frequency. PD most commonly occurs at the patient's home. (Although PD can be furnished within an ESRD facility, it is very rare. For purposes of this RFI, we consider PD to be exclusively a home modality.) Assuming that either modality would be clinically appropriate, whether a patient selects HD or PD may depend on a number of factors, such as patient education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference.[263] [264]

When Medicare began coverage for individuals with ESRD in 1973, more than 40 percent of dialysis patients in the U.S. were on home hemodialysis (HHD). More favorable reimbursement for outpatient dialysis and the introduction in the 1970s of continuous ambulatory peritoneal dialysis, which required less intensive training, contributed to a relative decline in HHD utilization.[265] Overall, the proportion of home dialysis patients in the U.S. declined from 1988 to 2012, with the number of home dialysis patients increasing at a slower rate relative to the total number of all dialysis patients. As cited in a U.S. Government Accountability Office (GAO) report, according to U.S. Renal Data System (USRDS) data, approximately 16 percent of the 104,000 dialysis patients in the U.S. received home dialysis in 1988; however, by 2012, the rates of HHD and PD utilization were 2 and 9 percent, respectively.[266]

Currently, the majority of ESRD patients receiving dialysis receive HD in an ESRD facility. At the end of 2016, 63.1 percent of all prevalent ESRD patients—meaning patients already diagnosed with ESRD—in the U.S. were receiving HD, 7.0 percent were being treated with PD, and 29.6 percent had a functioning kidney transplant.[267] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used HHD.[268] We note that once they are stable on a specific modality, patients are infrequently aware that they are able to change modalities. In 2018, 72 percent of Black ESRD patients received in-center hemodialysis versus only 57 percent of White patients. This data point may indicate that a greater number of white ESRD patients receive home dialysis than Black patients.[269]

Research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center. Key factors that may be related to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for

[262] ASPE Report, Advancing American Kidney Health, p. 24. Available at *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

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[266] United States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO–16–125). October 2015.

[267] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[268] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[269] National Kidney Foundation. *https://www.kidney.org/news/newsroom/fsindex.* Accessed 11/15/2021.

dialysis providers for providing home dialysis.[270] [271] [272] [273] [274]

We believe that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD beneficiaries. In fact, recent studies show substantial support among nephrologists and patients for dialysis treatment at home.[275] [276] [277] [278] [279] Although some measures in the ESRD QIP apply to home dialysis facilities, certain measures do not apply to facilities that have high rates of home dialysis. For example, home dialysis facilities are generally not eligible for scoring on the ICH–CAHPS measure, the Long-Term Catheter Rate clinical measure, the Standardized Fistula Rate measure, and the NHSN BSI clinical measure. Therefore, many of these facilities are eligible for fewer measures than facilities that provide in-center hemodialysis only. As increasing numbers of ESRD patients use home dialysis therapies,[280] we are interested in learning more about potential indicators of quality of care for home dialysis patients that are not currently being captured by the ESRD QIP. Therefore, we are seeking comments on strategies to monitor and assess the quality of care delivered to patients who receive dialysis at home. We are also seeking comments on how to support more equitable access to home dialysis across different ESRD patient populations.

We welcome comments on these issues.

2. Request for Information on Potential Future Inclusion of Two Social Drivers of Health Measures

(1) Background

Our commitment to supporting facilities in building equity into their healthcare delivery practices centers on empowering their workforce to recognize and eliminate health disparities that disproportionately impact people with ESRD, such as, individuals who are members of racial and ethnic minority groups, have low incomes, and/or reside in rural areas. In the CY 2022 ESRD PPS final rule, we noted our intention to initiate additional request(s) for information (RFIs) on closing the health equity gap, including identification of the most relevant social risk factors for people with ESRD (86 FR 61930). Health-related social needs (HRSNs), defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[281] We believe that consistently pursuing identification of HRSNs would have two significant benefits. First, because social risk factors disproportionately impact underserved communities, promoting screening for these factors could serve as evidence-based building blocks for supporting facilities and health systems in actualizing commitment to address disparities, improve health equity, and implement associated equity measures to track progress.[282] Second, these measures could support ongoing quality improvement initiatives by providing data with which dialysis providers would be able to stratify patient risk and organizational performance.

We are investigating potential integration of screening for health-related social needs into the ESRD QIP measure set. This type of screening was the subject of the recently ended Accountable Health Communities (AHC) Model, which was implemented by the CMS Innovation Center.[283] The Innovation Center developed the AHC Model based on evidence that addressing health-related social needs (HRSNs) through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.[284] HRSNs, defined as individual-level social conditions that negatively impact a person's health, are significant risk factors associated with adverse health outcomes and increased healthcare utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.[285] [286] Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.[287] [288] [289]

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[281] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed: November 23, 2021.

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[283] Additional information about the Accountable Health Communities Model is available at: *https://innovation.cms.gov/innovation-models/ahcm.*

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We believe consistent identification of HRSNs among people with ESRD would have two significant benefits that would contribute to reduction in health disparities and improvements in quality and efficiency of dialysis care delivery. First, due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities and health systems in addressing persistent disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, these measures would support ongoing quality improvement initiatives, specifically, care coordination for ESRD patients, by providing data with which to potentially stratify quality performance in dialysis providers. This is especially relevant in settings where a disproportionate number of patients have HRSNs and adverse healthcare outcomes, including hospital readmissions, that result in higher penalties related to diminished quality performance.[290] [291] We believe these measures align with *The CMS Quality Strategy Goals* around effective care coordination and prevention and treatment of chronic conditions.[292] We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority.[293] In this proposed rule, we seek public comment on the potential future inclusion of two related measures discussed later in this section.

(2) Screening for Social Drivers of Health Measure

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.[294] [295] The COVID–19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and healthcare utilization in the United States.[296] [297] Individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely to reduce CKD risk through recommended treatment goals.[298] [299] [300] [301] Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.[302] Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.[303] Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and healthcare utilization and costs.[304] [305] [306] [307] Of particular concern among people with ESRD are barriers to treatment prior to and after diagnosis, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.[308] [309]

We believe improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD and quality performance for dialysis and other healthcare providers. Recognizing the importance of social drivers of health, this year we have proposed to include social drivers of health screening measures in the Hospital Inpatient Quality Reporting Program (87 FR 28497 through 28506). We believe that screening for social drivers of health would similarly help inform facilities and other healthcare providers of the impact of HRSNs in people with ESRD, including their health outcomes and healthcare utilization. The measure would assess the proportion of adult patients who are screened for social drivers of health in five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

The goal is to lay the groundwork for potential future measures that focus on the development of an action plan to address these HRSNs, including efficiently navigating patients to available resources and strengthening the system of community-based supports where resources are lacking. Collecting baseline data via this measure would be crucial in informing design of future measures that could enable us to set appropriate performance targets. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities. We are exploring potential future inclusion of social

[290] National Academies of Sciences, Engineering, and Medicine.2017. *Accounting for social risk factors in Medicare payment.* Washington, DC: The National Academies Press. doi: 10.17226/23635.

[291] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[292] Centers for Medicare & Medicaid Services. (2021) CMS' Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[293] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[294] United States Renal Data System. 2021 *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, 2021.

[295] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[296] Centers for Disease Control. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[297] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[298] United States Renal Data System. 2021 *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, 2021.

[299] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[300] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[301] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[302] Norton, J.M., Moxey-Mims, M.M., Eggers, P.W., Narva, A.S., Star, R.A., Kimmel, P.L., & Rodgers, G.P. (2016). Social Determinants of Racial Disparities in CKD. Journal of the American Society of Nephrology: JASN, 27(9), 2576–2595. *https://doi.org/10.1681/ASN.2016010027.*

[303] CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.*

[304] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[305] Dean, E.B., French, M.T., Mortensen, K. (2020). Health Services Research 55 (Supplement 2): 883–893. doi: 10.1111/1475–6773.13283.

[306] Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. Diabetes Care 41: 933–939. *https://doi.org/10.2337/dc17-1812.*

[307] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385.*

[308] *Ibid.*

[309] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

drivers of health screening measures to the ESRD QIP. Therefore, we are seeking public comment on adding a new measure, Screening for Social Drivers of Health, to the ESRD QIP measure set in the next rulemaking cycle. The measure would assess the proportion of a facility's patients that are screened for one or more social drivers of health in the five core domains.

We believe facilities should screen for HRSNs among their patients to assess and increase the effectiveness of care coordination. Referral to community-based organizations can potentially reduce avoidable hospitalizations and disruptions to dialysis care. Data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.[310] [311] We believe screening for HRSNs like transportation in people with ESRD and targeted care coordination that links them to community-based services could improve health outcomes in this population. We also believe that publishing social drivers of health screening rates would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization. Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions.''

(3) Screen Positive Rate for Social Drivers of Health Measure

We believe it is important to screen patients with ESRD for HRSNs that can negatively impact health outcomes and contribute to avoidable hospitalizations. Unmet HRSNs can interrupt dialysis treatment and other routine care, including preventive health screenings, that is essential for ESRD-related conditions. Many patients treated in ESRD facilities have other chronic conditions that require consistent, multidisciplinary care to maintain their health.[312] [313] Household food insecurity has been associated with reliance on energy-dense foods which increase risks for onset of diabetes and hypertension, the leading causes of ESRD.[314] Housing instability and transportation difficulties both contribute to interruptions in dialysis care which leads to avoidable hospitalizations.[315] [316] Additionally, the COVID–19 pandemic has highlighted associations between disproportionate health risk, hospitalization, and adverse health outcomes.[317] [318] Capturing HRSN data may facilitate strengthening of linkages between facilities, medical providers (inpatient and outpatient), and community-based organizations which potentially could enhance care coordination for this group. Therefore, we are seeking public comment on the possible addition of a new measure, Screen Positive Rate for Social Drivers of Health, to the ESRD QIP measure set in future rulemaking. The measure would assess the proportion of patients who screen positive for HRSNs in five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. We also believe that publishing screen positive rates for social drivers of health would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization. Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions.''

We welcome public comment on potentially adding these two related Social Drivers of Health measures to the ESRD QIP measure set. We also welcome public comment on data collection, submission, and reporting for these two measures.

3. Request for Information on Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

a. Background

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to a racial or ethnic minority group; being a member of a religious minority; living with a disability; being a member of the LGBTQ+ community; living in a rural area; or being near or below the poverty level, are often associated with worse health outcomes.[319] [320] [321] [322] [323] [324] [325] [326] [327] We are committed to achieving equity in healthcare outcomes for our

[310] *Ibid.*

[311] United States Renal Data System. 2021 *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, 2021.

[312] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[313] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[314] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203–212, doi: 10.3945/an.112.003277.

[315] United States Renal Data System. 2021 *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, 2021.

[316] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385.*

[317] Centers for Disease Control. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[318] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[319] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[320] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[321] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. British Medical Journal, 346.

[322] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[323] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[324] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-incomehealth-status-recap.pdf.*

[325] HHS Office of Minority Health. (2020). Progress Report to Congress: 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[326] Heslin, KC, Hall, JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2021;70:149–154. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[327] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. medRxiv. 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327.

beneficiaries by supporting healthcare providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities.[328]

Health equity is an important component of an equitable society. Equity, as defined in Executive Order 13985, is ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [329]

We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, religion, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[330]

Such disparities in health outcomes and healthcare access are the result of multiple factors including differences in access to routine dialysis and primary care which contribute to health disparities among patients with ESRD. We discussed the impact of these disparities on patients with ESRD in our request for information on closing the health equity gap in the CY 2022 ESRD PPS proposed rule (86 FR 36362). Because we are working toward the goal of all ESRD patients receiving high quality dialysis treatment and other healthcare, irrespective of individual characteristics, we are committed to supporting dialysis providers and health systems in building a culture of equity that focuses on educating and empowering the healthcare workforce to recognize and eliminate health disparities in ESRD patients.[331]

Closing the health equity gap would require multipronged approaches that effectively address the many drivers of health disparities. As summarized in the CY 2022 ESRD PPS final rule request for information, we noted our intention to initiate additional request(s) for information (RFIs) on closing the health equity gap, including identification of the most relevant social risk factors for people with ESRD (86 FR 61930). Advancing health equity would require a variety of efforts across the healthcare system. The reduction in healthcare disparities is one aspect of improving equity that we have prioritized. In the CY 2022 ESRD PPS final rule request for information, ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' (86 FR 61928 through 61937), we described programs and policies we have implemented over the past decade with the aim of identifying and reducing healthcare disparities, including: the CMS Mapping Medicare Disparities Tool [332] and the CMS Disparity Methods stratified reporting.[333] CMS has also begun efforts supporting implementation of the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (78 FR 58539); [334] as well as improvement of the collection of social determinants of health in standardized patient assessment data in four post-acute care settings and the collection of health-related social need data by model participants in the CMMI Accountable Health Communities Model.[335] [336] [337]

Measuring healthcare disparities and reporting these results to healthcare providers is a cornerstone of our approach to advancing healthcare equity. It is important to consistently measure differences in care received by different groups of our beneficiaries, and this can be achieved by methods to stratify quality measures. Measure stratification is defined for this purpose as calculating measure results for specific groups or subpopulations of patients. Assessing healthcare disparities through stratification is only one method for using healthcare quality measurement to address health equity, but it is an important approach that allows healthcare providers to tailor quality improvement initiatives, decrease disparity, track improvement over time, and identify opportunities to evaluate upstream drivers of health. The use of measure stratification to assess disparities has been identified by CMS Office of Minority Health (CMS OMH) as well as by external organizations such as the American Hospital Association as a critical component of an organized response to health disparities.[338] [339] To date, we have performed analyses of disparities in our quality programs by using a series of stratification methodologies identifying quality of care for patients with heightened social risk or with demographic characteristics with associations to poorer outcomes.

As efforts to improve methods and sources of social determinant and demographic data collection mentioned previously are ongoing, we would continue to evaluate opportunities to expand these current measure stratification reporting initiatives with existing sources of data. We aim to provide comprehensive and actionable information on health disparities to healthcare providers participating in our quality programs, in part, by starting with confidential reporting of stratified measure results that highlight potential gaps in care between groups of patients

[328] Centers for Medicare and Medicaid Services. (2016). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[329] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[330] Centers for Medicare & Medicaid Services. (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[331] Centers for Medicare and Medicaid Services. (2016). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[332] Centers for Medicare and Medicaid Services. (2021). CMS Office of Minority Health. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[333] Centers for Medicare and Medicaid Services. Disparity Methods Confidential Reporting. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

[334] *https://www.federalregister.gov/documents/2013/09/24/2013-23164/national-standards-for-culturally-and-linguistically-appropriate-services-clas-in-health-and-health.*

[335] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Model. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[336] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[337] Centers for Medicare and Medicaid Services. (2021). IMPACT Act Standardized Patient Assessment Data Elements. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Patient-Assessment-Data-Elements.*

[338] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[339] Improving Health Equity Through Data Collection and Use: A Guide for Hospital Leaders. (2011). Available at: *http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.*

using existing data sources. This includes examining and reporting disparities in care across additional social risk factors and demographic variables associated with historic disadvantage in the healthcare system, and examining disparities across additional healthcare quality measures, and in new care settings. As disparity measurement initiatives expand through the use of measure stratification, it is important to model efforts off of existing best practices by continuing to gather stakeholder feedback and to make use of lessons learned in the development of existing disparity reporting efforts.

Specific efforts aimed at closing the health equity gap in ESRD patients include the *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams in order to enhance care for medically underserved patients with CKD and are at risk of progression of disease or complications,[340] and the CMS ETC Model, which aims to test the effectiveness of adjusting certain Medicare payments to encourage more home dialysis and kidney transplants, support beneficiary modality choice, and preserve or improve quality of care provided to ESRD beneficiaries while reducing Medicare expenditures.[341]

Measuring healthcare disparities and reporting the results to dialysis providers is under consideration as a central component of our approach to closing the health equity gap in patients with ESRD. Stratification of quality measures would facilitate consistent measurement of differences in care received and subsequent outcomes by different groups of patients. Stratification is one of several methodological approaches to estimating health disparities that would support facilities in tailoring quality improvement initiatives to reduce disparities and track improvement over time. We have identified stratification as a critical component of an organized response to health disparities.[342] [343] To date, we have employed stratification techniques in a few programs to evaluate quality of care for patients with disproportionate social risk burden and demographic characteristics associated with adverse health outcomes. For example, in the FY 2018 IPPS/LTCH PPS final rule, the Hospital Inpatient Quality Reporting Program introduced confidential reporting of hospital quality measure data stratified by dual eligibility (82 FR 38403 through 38409).

As efforts to improve methods and sources of social determinant and demographic data collection are ongoing, we intend to continue to evaluate opportunities to expand these current measure stratification reporting initiatives with existing sources of data. We anticipate expanding our efforts to provide comprehensive and actionable information on health disparities to dialysis providers participating in the ESRD QIP by providing measure stratification results to highlight potential gaps in care among patient groups. This includes examining and reporting disparities in care across specific social risk factors and demographic variables associated with historic disadvantage in ESRD care in particular and examining disparities across ESRD QIP measures. We aim to gather feedback from technical experts and dialysis providers as we evaluate existing best practices for measure stratification methods and reporting approaches applied to health disparity evaluation. As disparity measurement initiatives expand through the use of measure stratification, it is important to model efforts off of existing best practices by continuing to gather stakeholder feedback and to make use of lessons learned in the development of existing disparity reporting efforts.

There are several key considerations that we intend to consider when advancing the use of measurement and stratification as tools to address healthcare disparities and advance healthcare equity. We seek input on key considerations in five specific areas that could inform our approach. Each is described in more detail later in this section:

- *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in ESRD QIP*—This section identifies the approaches for measuring healthcare disparities through measure stratification in CMS quality reporting programs.
- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting*—This section describes considerations that could inform the selection of ESRD QIP measures to prioritize for stratification.
- *Principles for Social Risk Factor and Demographic Data Selection and Use*—This section describes social risk factor and demographic data that we would consider investigating for use in stratifying ESRD QIP measures for healthcare disparity measurement. Dialysis and other healthcare providers would use their own demographic data to address disparities affecting their patients.
- *Identification of Meaningful Performance Differences*—This section reviews several strategies for identifying meaningful differences in performance when ESRD QIP measures apply stratification or disparity reporting that are easily understood but remain useable by dialysis providers.
- *Guiding Principles for Reporting Disparity Results*—This final section reviews considerations we would take into account in determining how ESRD QIP would report disparity results to dialysis providers, as well as the ways different reporting strategies would hold providers accountable.

We would then solicit public input on these topics.

b. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in ESRD QIP

Our goal in developing methods to measure disparities in care is to provide actionable and useful results to dialysis providers. By quantifying healthcare disparities (that is, through quality measure stratification), we aim to provide useful tools for dialysis providers and facilities to drive improvements. We believe these results would support dialysis providers and facilities efforts in examining the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions. With stratified disparity information available, it may be possible to drive system-wide advancement through incremental, provider-level improvement.

There are multiple conceptual approaches to stratifying measures for reporting health disparities. In recent years, we have focused on identifying healthcare disparities by reporting stratified results for acute care hospitals in two complementary ways. First, stratification by a given social risk factor or demographic variable has generated measure results for subgroups of patients cared for by individual providers that can be directly compared. This type of comparison identifies important disparities, such as gaps in care and outcomes between patient groups. This approach is sometimes referred to as ''within-provider'' disparity. This can be done for most

[340] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[341] CMS (2021). ESRD Treatment Choices (ETC) Model. Available at: *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

[342] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[343] *http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.*

measures that include patient-level data and can be helpful to quantitatively express a provider's disparity in care. However, similar to the measure itself, the approach to perform this type of comparison would differ based on the measure's complexity. For example, when risk adjustment is used in the measure, the stratification approach would have to be adapted to address clinical risk adjustment.[344] Second, a provider's performance on a measure for only the subgroup of patients with that social risk factor can be compared to other providers' performance for that same subgroup of patients (sometimes referred to as ''across-provider'' disparities measurement). This type of comparison illuminates the healthcare provider's performance for only the population with a given social risk factor, allowing comparisons for specific performance to be better understood and compared to peers or state and national benchmarks. These approaches are reviewed and recommended by The Assistant Secretary of Planning and Evaluation (ASPE) as ways to measure health equity in their 2020 Report to Congress.[345]

Alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance can give detailed information about where differences in care exist. For example, a dialysis provider may underperform when compared to national averages for patients with a given risk factor, but if they also underperform for patients without that risk factor, the measured difference, or disparity in care, could be negligible even though performance for the group historically underserved group remains poor. In this case, simply stratifying the measure results could show little difference in care between patient groups within the facility, comparing results for only the group that has been historically marginalized would signal the need to improve care for this population.

We are especially sensitive to the need to ensure all disparity reporting avoids measurement bias. Stratified results must be carefully examined for potential measurement or algorithmic bias that is introduced through stratified reporting.[346] Furthermore, results of stratified reporting must be evaluated for any type of selection bias that fails to capture disparity due inadequate representation of subgroups of patients in measure cohorts. During measure re-evaluation, we would aim to carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusion from results.

c. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

We intend to begin our efforts to provide stratified reporting for ESRD QIP measures, provided they offer meaningful and valid feedback to dialysis and other healthcare providers on their care for ESRD patients that may face social disadvantage or other forms of discrimination or bias. Further development of stratified reporting of ESRD QIP measures can provide dialysis and other healthcare providers with more granular results that support targeting resources and initiatives to improve health equity. We are mindful that it may not be possible to calculate stratified results for all ESRD QIP measures, or there may be situations where stratified reporting may not be desired. To help inform prioritization of the candidate ESRD QIP measures for stratified reporting, we aim to receive feedback on several systematic principles under consideration that we believe would help us prioritize measures for disparity reporting across programs.

These considerations, when assessed within the context of specific programs, like the ESRD QIP, help gauge the utility and potential uses of stratified measure results to provide usable and impactful information on disparity broadly across our programs. While we aim to standardize approaches where possible, we also recognize that the variety of measures and care settings involved and the contextual nature of stratified reporting would require decisions to be made at the program level.

We have developed the following guiding principles for prioritizing ESRD QIP measures for disparity reporting:

• *Prioritize validated clinical quality measures*—When considering disparity reporting of stratified quality measures, there are several advantages to focusing on recognized measures which have met industry standards for measure reliability and validity. First, existing measures highlight agreed upon priority areas for quality measurement specific to the program setting, which have been developed under adherence to the CMS Measures Management System Blueprint [347] and have been reviewed for their clinical and population relevance by experts knowledgeable about the nuances of care delivered in these settings. Furthermore, these measures have been reviewed for clinical significance, applicability, and scientific rigor by additional organizations, such as the National Quality Forum (NQF), and have been selected for inclusion in programs with their recommendations in mind. Adapting these existing tools to measure disparity through stratification maintains adherence to predefined measurement priorities and utilizes a great deal of extant expert and methodological validation. The application of stratified reporting to validated clinical quality measures which are used across the healthcare sector also aim to mitigate any potential additional administrative burden on healthcare providers, hospitals, and facilities.

• *Prioritizing Measures with Identified Disparity in Treatment or Outcomes Among Participating Facilities for Selected Social or Demographic Factors*—Candidate ESRD QIP measures for stratification should be supported by evidence of underlying healthcare disparities in the procedure, condition, or outcome being measured. A review of peer-reviewed research studies should be conducted to identify disparities related to treatment or procedure the measure evaluates, or outcome used to score the measure, and should carefully consider both social risk factors and patient demographics. Disparity related to the measure could be based on the outcome or procedures and practices assessed by the measure. In addition, analysis of Medicare-specific data should be done in order to demonstrate evidence of disparity in care for some or most healthcare providers that treat Medicare patients. In addition to disparities in outcomes and quality, consideration should also be given to conditions that have highly disproportionate prevalence in certain populations.

• *Prioritize Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons*—Sample

[344] Centers for Medicare & Medicaid Services. (2015). Risk Adjustment Fact Sheet. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Risk-Adjustment-Fact-Sheet.pdf.*

[345] ASPE. (2020). Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program: The Second of Two Reports Required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195191/Second-IMPACT-SES-Report-to-Congress.pdf.*

[346] Obermeyer Z., Powers B., Vogeli C., Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019;366(6464):447–53.

[347] Centers for Medicare and Medicaid Services. (2020). CMS Measures Management System Blueprint (Blueprint v 16.0).Available at: *https://www.cms.gov/Medicare/QualityInitiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

size holds specific significance for statistical calculations; however, it holds additional importance in the context of disparity reporting. Candidate measures for stratification would need to have sufficient sample size of enrollees to ensure that reported results of the disparity calculation are reliable and representative. This may be challenging if cohorts with a given social risk factor are small.

ESRD QIP may further consider measures for disparity reporting based on the utility of the stratified information, namely, prioritizing measures for stratification that show large differences in care between patient groups. Large differences in care for patients along social or demographic lines may indicate high potential that targeted initiatives could be effective. This is only one consideration in identifying the most meaningful differences in care, however, as initiatives designed for measures that show small disparities, but have very large cohorts, may have very large aggregate impacts on the national scale.

- *Prioritize Outcome Measures and Measures of Access and Appropriateness of Care*—Quality measurement in CMS programs often focus on outcomes of care, such as mortality or readmission, as high priority quality measures. For example, two key ESRD QIP outcome measures are the SHR clinical measure and the SRR clinical measure, which we are updating so that the measure results are expressed as rates. Such outcome measures remain a priority in the context of disparities measurement. However, measures that focus on access, when available, are also critical tools for addressing healthcare disparities. Measures that address healthcare access can counterbalance the risk of creating perverse incentives, for example, whereby a facility may improve its performance on existing quality measures by limiting access to care for populations who are historically underserved.

To complement measure stratification focused on clinical outcomes, the ESRD QIP would consider prioritizing measures with a focus on access to or appropriateness of care. These measures, when reported in tandem with clinical outcomes, would provide a broader picture of care provided at a facility, illuminate potential performance drivers, and identify organizations that fail to address access to care barriers for patient sub-groups. We acknowledge that the measurement of access and appropriateness of care is a growing field, and quality measures in these areas are limited. However, as our ability to measure these facets of healthcare improve, they would be high priority for measure stratification.

d. Principles for Social Risk Factor and Demographic Data Selection and Use

There are numerous non-clinical drivers of health associated with patient outcomes, including social risk factors such as socioeconomic status, housing availability, and nutrition, as well as marked inequity in outcomes based on patient demographics such as race and ethnicity, being a member of a minority religious group, geographic location, sexual orientation and gender identity, religion, and disability status.[348] [349] [350] [351] [352] [353] [354] [355] The World Health Organization (WHO) defines social risk factors as ''non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life.'' [356] These include factors such as income, education, job insecurity, food insecurity, housing, social inclusion and non-discrimination, access to affordable health services, and any others. Research has indicated that these social factors may have as much or more impact on health outcomes as clinical care itself.[357] [358] Additionally, differences in outcomes based on patient race and ethnicity have been identified as significant, persistent, and of high priority for CMS and other federal agencies.[359]

In prioritizing among social risk factors and demographic variables, disability, and other markers of disadvantage for stratified reporting, the ESRD QIP would develop approaches that have the most relevance for the existing measure set. Patient reported data are considered to be the gold standard for evaluating care for patients with social risk factors or who belong to certain demographic groups as this is the most accurate way to attribute social risk.[360] Although some of this information is currently reported on Form 2728—ESRD Medical Evidence Report Medicare Entitlement And/Or Patient Registration (OMB control number 0938–0046), we believe that additional development of patient-reported social risk factor and demographic variable data sources may be necessary to collect data that is complete enough to consider for disparity reporting. Currently, there are many efforts underway to further develop data collection for self-reported patient social risk and demographic variables. Yet, given that data sources are small, they may only have the ability to provide statistically significant disparity results for a small proportion of care facilities.

We would continue to evaluate patient-reported sources of social risk and demographic information. Until validated data are available, we are considering three sources of social risk and demographic data that would allow us to report stratified measure results:

[348] Joynt KE, Orav E, Jha AK (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[349] Lindenauer PK, Lagu T., Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: retrospective cohort study. British Medical Journal, 346.

[350] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[351] Polyakova, M, et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[352] Rural Health Research Gateway. (2018). Rural communities: Age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-incomehealth-status-recap.pdf.*

[353] HHS Office of Minority Health (2020). 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[354] Poteat TC, Reisner SL, Miller M, Wirtz AL (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. medRxiv [Preprint]. 2020.07.21.20159327. doi: 10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[355] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[356] World Health Organization. Social Determinants of Health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.*

[357] Hood, C., Gennuso K., Swain G., Catlin B. (2016). County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. Am J Prev Med. 50(2):129–135. doi:10.1016/j.amepre.2015.08.024.

[358] Chepaitis, A.E., Bernacet, A., Kordomenos, C., Greene, A.M., Walsh, E.G. (2020). Addressing social determinants of health in demonstrations under the financial alignment initiative. RTI International. Available at: *https://innovation.cms.gov/data-and-reports/2021/fai-sdoh-issue-brief.*

[359] White House. (2021). Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[360] Jarrín OF, Nyandege AN, Grafova I B, Dong X., Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

• *Billing and Administrative Data*—The majority of quality measurement tools used in our quality programs focus on utilizing existing enrollment and claims data for Medicare beneficiaries. Using these existing data to assess disparity, for example by the use of dual enrollment for Medicare and Medicaid, allows for high impact analyses with negligible facility burden. There are, however, limitations in these data's usability for stratification analysis. Our current administrative race and ethnicity data have been shown to have historical inaccuracies due to limited collection classifications and attribution techniques, and are generally considered not to be accurate enough for stratification and disparity analyses.[361] International Classification of Diseases,10th Revision (ICD–10) codes for socioeconomic and psychosocial circumstances (''Z codes'' Z55 to Z65) represent an important opportunity to document patient-level social risk factors in Medicare beneficiaries, however, they are rarely used in clinical practice, limiting their usability in disparities measurement.[362] If the collection of social risk factor data improves in administrative data, we would continue to evaluate its applicability for stratified reporting in the future.

Dual eligibility is a widely used proxy for low socioeconomic status and is an exception to the previously discussed limitations, making it an effective indicator for worse outcomes due to low socioeconomic status. The use of dual eligibility in social risk factor analyses was supported by ASPE's First and Second Reports to Congress.[363] [364] These reports found that in the context of VBP programs, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

• *Area-based Indicators of Social Risk Information and Patient Demographics*—Area-based indicators pool area-level information to create approximations of patient risk or describe the neighborhood or context that a patient resides in. Popular among them are the use of the American Community Survey (ACS), which is commonly used to attribute social risk to populations at the ZIP code or Federal Information Processing Standards (FIPS) county level. Several indices, such as the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index,[365] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Social Vulnerability Index (CDC/ATSDR SVI),[366] and Health Resources and Services Administration Area Deprivation Index,[367] combine multiple indicators of social risk into a single score which can be used to provide multifaceted contextual information about an area and may be considered as an efficient way to stratify measures that include many social risk factors.

• *Imputed Sources of Social Risk Information and Patient Demographics*—Imputed data sources use statistical techniques to estimate patient-reported factors, including race and ethnicity. In the case of race and ethnicity, indirect estimation improves upon imperfect and incomplete data by drawing on information about a person's name and address and the linkage of those variables to race and ethnicity. One such tool is the Medicare Bayesian Improved Surname Geocoding (MBISG) method (currently in version 2.1), which combines information from administrative data, surname, and residential location to estimate patient race and ethnicity.[368] This tool was originally developed by the RAND Corporation, and further customized for the Medicare population to improve existing CMS administrative data on race and ethnicity.

The MBISG 2.1 method does not assign a single race and ethnicity to an individual; instead, it generates a set of six probabilities, each estimating what the individual would self-identify as given a set of racial and ethnic groups to choose from including: American Indian or Alaska Native, Asian or Pacific Islander, Black, Hispanic, Multiracial, and White. In no case would the estimated probability be used for making inferences about a beneficiary; only self-reported data on race and ethnicity should be used for that purpose. However, in aggregate, these results can provide insight and accurate information at the population level, such as the patients of a given facility, or the members of a given plan. MBISG 2.1 is currently used by CMS' OMH to undertake various analyses, such as comparing scores on clinical quality of care measures from the Healthcare Effectiveness Database and Information Set (HEDIS) by race and ethnicity for Medicare Part C/D health plans, and in developing a Health Equity Summary Score (HESS) for Medicare Advantage (MA) health plans.[369]

While the use of area-based indicators and imputed data sources are not meant to replace efforts to improve patient-level data collection, we are considering how they might be used to quickly begin population-level disparity reporting of stratified measure results while being conscientious about data limitations.

Imputed data sources, particularly when used to identify patient populations for measurement, must be carefully evaluated for their potential to negatively affect the populations being studied. For this reason, imputed data sources should only be considered after significant validation study has been completed, including evaluation by key stakeholders for face validity, and any calculations that incorporate these

[361] Jarrín OF, Nyandege AN, Grafova IB., Dong X., Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[362] Centers for Medicare & Medicaid Services, Office of Minority Health. (2021). Utilization of Z codes for social determinants of health among Medicare fee-for-service beneficiaries, 2019. Available at: *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[363] Office of the Assistant Secretary for Planning and Evaluation. (2016). Social risk factors and performance under Medicare's value-based purchasing programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[364] Office of the Assistant Secretary For Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[365] Bonito A., Bann C., Eicheldinger C., Carpenter L. (2008). Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality.

[366] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management, 8(1). Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.*

[367] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[368] Haas A., Elliott M.N., Dembosky J.W., Adams J.L., Wilson-Frederick S.M., Mallett J.S. et al. (2019). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res, 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3. PMID: 30506674; PMCID: PMC6338295. Available at: *https://pubmed.ncbi.nlm.nih.gov/30506674/.*

[369] Agniel D., Martino S.C., Burkhart Q., Hambarsoomian K., Orr N., Beckett M.K, et al. (2021). Incentivizing excellent care to at-risk groups with a health equity summary score. J Gen Intern Med, 36(7):1847–1857. doi: 10.1007/s11606–019–05473–x. Epub 2019 Nov 11. PMID: 31713030; PMCID: PMC8298664. Available at: *https://pubmed.ncbi.nlm.nih.gov/31713030/.*

methods should be continuously evaluated for the accuracy of their results and the necessity of their use. While neither imputed nor area-level geographic data should be considered a replacement for improved data collection, researchers have found their use to be a simple and cost-efficient way to make general estimations of social risk at a community level.[370] Even more potent, when patient-level information is not available, are the combination of several sources of imputed or area-level data to provide diverse perspectives on social risk of a population.

e. Identification of Meaningful Performance Differences

In examining potential ways to report disparity data in the ESRD QIP, including the results of quality measure stratification, we would consider different approaches to identifying meaningful differences in performance. Stratified results can be presented in a number of ways to describe to providers how well or poorly they are performing, or how they perform when compared to other care facilities. For this reason, it is important to identify how best to present meaningful differences in performance for measures of disparity reporting. We aim to provide information that offers meaningful information to dialysis providers. While we aim to use standardized approaches where possible, identifying differences in performance on stratified results would be made at the program level due to contextual variations across programs and settings. We look forward to feedback on the benefits and limitations of the possible reporting approaches we have described in this Request for Information.

- *Statistical Differences*—When aiming to examine differences in disparities results among facilities, the use of statistical testing can be helpful. There are many statistical approaches that can be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm. Importantly, these approaches may result in groupings that are statistically different, but not meaningfully different depending on the distribution of results.
- *Rank Ordering and Percentiles*—Ordering healthcare providers in a ranked system is another option for reporting disparity results in a meaningful way. In this system, facilities could be ranked based on their performance on disparity measures to quickly allow them to compare their performance to other similar healthcare providers. This approach works well as a way for facilities to easily compare their own performance against others; however, a potential drawback is that it does not identify the overall magnitude of disparity. For example, if a measure shows large disparity in care for patients based on a given factor, and that degree of disparity has very little variation between healthcare providers, the difference between the top and bottom ranked facilities would be very small even if the overall disparity is large.
- *Threshold Approach*—A categorization system could also be considered for reporting disparity results. In this system, facilities could be grouped based on their performance using defined metrics, such as fixed intervals of results of disparity measures, indicating different levels of performance. Using a categorized system may be more easily understood by stakeholders by giving a clear indication that outcomes are not considered equal. However, this method does not convey the degree of disparity between facilities or the potential for improvement based on the performance of other facilities. Furthermore, it requires a determination of what is deemed 'acceptable disparity' when developing categories.
- *Benchmarking*—Benchmarking, or comparing individual results to, for example, state or national averages, is another potential reporting strategy. This type of approach could be done, especially in combination with a ranked or threshold approach, to give facilities more information about how they compare to the average care for a patient group.

Another consideration for each of these approaches is grouping similar care settings together for comparison through a peer grouping step, especially if a ranked system is used to compare facilities. Stakeholders have argued that comparisons between facilities have limited meaning if the facilities are not similar, and that peer grouping would improve their ability to interpret results. Overall, the value of peer grouping must be weighed against the potential to set different standards of meaningful disparity among different care settings.

f. Guiding Principles for Reporting Disparity Results

There are several options for reporting of disparity results to drive improvements in quality. Confidential reporting, or reporting results privately to providers, is an approach we have used for new newly adopted measures in a CMS quality program to give providers an opportunity to become more familiar with calculation methods and to begin improvement activities before other forms of reporting. Providing early results to facilities is an important way to provide facilities the information they need to design impactful strategies to reduce disparity. Public reporting, or reporting results publicly, is a second reporting option. This method could provide ESRD QIP participants and ESRD patients with important information on facility quality, and by turn relies on market forces to incentivize healthcare providers to improve and become more competitive in their markets without directly influencing payment from CMS. Payment accountability could potentially offer a direct line for us to reward healthcare providers for having low disparity rates, or for performing well for medically underserved population groups.

We are exploring the most optimal methods of reporting disparity results. Initially, confidential reporting may be prudent for facilities and healthcare providers to understand stratification methodology and the presentation of stratified results, and to begin to implement programs to reduce disparities at their facilities. We are considering this approach to begin having an impact on disparity, while allowing providers time to interpret results and set up processes to address disparities.

It would be important to carefully consider the context of reporting, including measure specifications, data sources, care setting, and dialysis providers' and patients' perspectives before implementing a reporting strategy. Earlier in this RFI, we identified risks to applying stratification to all measures using all available social risk factor and demographic variables, such as the chance that unexpected results may exacerbate disparity. We intend to consider these risks compared to the benefits of different reporting strategies when developing implementation plans.

Regardless of the methods used to report results, it is important to report stratified measure data alongside overall measure results. Review of both measure results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing important information to drive quality improvement. Unstratified quality measure results address general differences in quality of care between

[370] Bi, Q., He, F., Konty, K., Gould, L.H., Immerwahr, S., & Levanon Seligson, A. (2020). ZIP code-level estimates from a local health survey: Added value and limitations. Journal of Urban Health: Bulletin of the New York Academy of Medicine, 97(4), 561–567.

healthcare providers and promote improvement for all patients, but unless stratified results are available, it is unclear if there are subgroups of patients that benefit most from initiatives. Notably, even if overall quality measure scores improve, without identifying and measuring differences in outcomes between groups of patients, it is impossible to track progress in reducing disparity for patients with heightened risk of poor outcomes.

g. Solicitation of Public Comments

The goal of this request for information is to describe key considerations that we would acknowledge when advancing the use of measure stratification as one quality measurement tool to address healthcare disparities and advance health equity in the ESRD QIP. This is important as a means of setting priorities and expectations for the use of stratified measures. We specifically note that several important factors may limit the use of stratification or may need to be taken into consideration.

We invite general comments on the principles and approaches listed previously, or additional thoughts about disparity measurement or stratification guidelines suitable for overarching consideration across our programs. Specifically, we invite comment on:

- Overarching goals for measuring disparity that should be considered across CMS quality programs, including: the importance of pairing stratified results to evaluate gaps in care among groups of patients attributed to a given facility and comparison of care for a subgroup of patients across facilities, and the goal that these stratified results are reported alongside overall measure results to have a comprehensive view of disparities.
- Principles to consider for prioritization of measures for disparity reporting, including prioritizing stratification for: valid clinical quality measures; measures with established disparities in care; measures that have adequate sample size and representation among facilities; and, measures that consider access and appropriateness of care.
- Principles to be considered for the selection of social risk factors and demographic data for use measuring disparities, including the importance of identifying new social risk factor and demographic variables to use to stratify measures. We also seek comment on the use of imputed and area based social risk and demographic indicators for measure stratification when patient reported data are unavailable.
- Preferred ways that meaningful differences in disparity results can be identified or should be considered.
- Guiding principles for the use and application of the results of disparity measurement, such as providing confidential reporting initially versus public reporting.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[371] CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021, and ending December 31, 2023.

The second payment adjustment under the ETC Model is the PPA. For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we will make an upward or downward adjustment to certain payments to the ETC participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959), and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994).

[371] ZIP code™ is a trademark of the United States Postal Service.

B. Proposed Updates to the ETC Model

1. Performance Payment Adjustment Achievement Scoring Methodology

Under the ETC Model, the PPA is a positive or negative adjustment on dialysis and dialysis-related Medicare payments for both home dialysis and in-center dialysis. To calculate an ETC Participant's PPA, we assess the ETC Participant's performance on the home dialysis rate and the transplant rate in relation to achievement and improvement benchmarks, as described in 42 CFR 512.370(b) and (c), respectively.

An ETC Participant's achievement is scored at the aggregation group level in relation to achievement benchmarks, which are constructed based on the home dialysis rate and transplant rate observed among aggregation groups located in Comparison Geographic Areas during corresponding Benchmark Years. Achievement benchmarks are percentile based, and set at the <30th, ≥30th, ≥50th, ≥75th, and ≥90th percentile of rates for Comparison Geographic Areas during the Benchmark Year. An ETC Participant receives the achievement points that that correspond with its performance, at the aggregation group level, on the home dialysis rate and transplant rate in relation to the achievement benchmarks, as described in § 512.370(b)(1).

In the CY 2022 ESRD PPS final rule, we modified the achievement benchmarking methodology such that, beginning MY3, achievement benchmarks are stratified based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries are dually eligible for Medicare and Medicaid or receive the Low Income Subsidy (LIS). Beginning MY3, we create two strata, with the cutpoint set at 50 percent of attributed beneficiary years being for attributed beneficiaries who were dual-eligible or received the LIS, as described in § 512.370(b)(2).

Based on subsequent analysis, we have found that stratifying achievement benchmarks in this way has increased the likelihood that the lowest benchmark—set at the 30th percentile—could be set at a home dialysis rate or transplant rate of zero. This change occurred because dividing the set of attributable beneficiaries in Comparison Geographic Areas into two strata means that there are fewer observations per strata, changing the underlying distributions.

Awarding achievement points for a home dialysis rate or transplant rate of zero is inconsistent with the design and goals of the ETC Model. The purpose of the ETC Model is to test the use of certain payment adjustments to increase rates of home dialysis and transplantation, thereby improving or maintaining quality and reducing Medicare expenditures. Awarding achievement points, which are used to determine the magnitude and direction of an ETC Participant's PPA, for a home dialysis rate or a transplant rate of zero is antithetical to the ETC Model's design.

To address this issue, we propose to further modify the achievement scoring methodology for the ETC Model. Specifically, we propose to add a requirement, to be codified in a new provision at § 512.370(b)(3), to specify that, beginning MY5, an ETC Participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate. We seek comment on this proposal.

2. Kidney Disease Patient Education Services

Under section 1861(ggg)(1) of the Act and § 410.48 of our regulations, Medicare Part B covers outpatient, face-to-face kidney disease patient education services provided by certain qualified persons to beneficiaries with Stage IV chronic kidney disease. As noted in the Specialty Care Models final rule, kidney disease patient education services play an important role in educating patients about their kidney disease and helping them make informed decisions on the appropriate type of care and/or dialysis needed for them (85 FR 61337). In addition, as we noted in the Specialty Care Models final rule, kidney disease patient education services are designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access (85 FR 61337).

Because kidney disease patient education services have been infrequently billed, we found it necessary for purposes of testing the ETC Model to waive select requirements of kidney disease patient education services as authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Specifically, to broaden the availability of kidney disease patient education services under the ETC Model, we used our authority under section 1115A(d) of the Act to waive certain requirements for individuals and entities that furnish and bill for kidney disease patient education services. We codified these waivers at § 512.397(b). These include waivers to allow a broader scope of beneficiaries to have access to kidney disease patient education services, as well as greater flexibility in how the kidney disease patient education services are performed. CMS also waived the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

Specifically, under § 512.397(b)(1), kidney disease patient education services may be provided by ''qualified staff,'' which includes any qualified person (as defined at § 410.48(a)) as well as clinical staff. In the CY 2022 ESRD PPS final rule (86 FR 61988), we defined ''clinical staff'' under 42 CFR 512.310 of our regulations to mean a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

In addition, in the CY 2022 ESRD PPS final rule, we added a new provision at § 512.397(c) permitting an ETC Participant to reduce or waive the 20 percent coinsurance requirement for kidney disease patient education services furnished on or after January 1, 2022, if several conditions are satisfied, including a requirement that the individual or entity that furnished the services is qualified staff and was not leased from or otherwise provided by an ESRD facility or related entity. We finalized this cost-sharing reduction policy because we believed this patient incentive would advance the ETC Model's goal of increasing access to kidney disease patient education services and make beneficiaries more aware of their choices in kidney treatment, including the choice of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis. We also determined that under § 512.397(c)(3), the federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and § 512.397(c)(1).

We recognized in the CY 2022 ESRD PPS final rule that ESRD facilities and other entities sometimes enter into arrangements with clinicians or other

parties to provide certain services (86 FR 61991). We also recognized that some ETC Participants may wish to furnish kidney disease patient education services using staff or other resources furnished under a contractual arrangement with an ESRD facility or other entity. We were concerned, however, that even if such arrangements were structured to comply with all applicable fraud and abuse laws, they could nevertheless result in program abuse. Specifically, such arrangements could operate to circumvent the statutory prohibition against ESRD facilities furnishing kidney disease patient education services. For example, the staff or resources furnished to the ETC Participant from an ESRD facility or related entity could be used to market a specific ESRD facility or chain of ESRD facilities to beneficiaries who may need to choose an ESRD facility in the future. We stated that we did not believe that ETC Participants should obtain safe harbor protection for the reduction or waiver of cost-sharing on kidney disease patient education services if such services were furnished by personnel leased from an ESRD facility or related entity. We explained that a ''related entity'' would include any entity that is directly or indirectly owned in whole or in part by an ESRD facility and that this policy aligns with the statutory provision that excludes ESRD facilities from the individuals and entities that can furnish kidney disease patient education services.

Currently, the prohibition against the furnishing of kidney disease patient education services by qualified staff who are leased from or otherwise provided by an ESRD facility or related entity does not apply unless an ETC Participant reduces or waives the beneficiary's coinsurance obligation for kidney disease patient education services. We propose that a similar prohibition would apply with respect to ''clinical staff'' regardless of whether the ETC Participant is reducing or waiving the kidney disease patient education coinsurance obligation. Specifically, we are proposing to add a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1) of our regulations, beginning for MY5, ''clinical staff'' may not be leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity. Applying this prohibition on ''clinical staff'' could also protect beneficiaries and their care choices, and limit the likelihood that the ''clinical staff'' furnished to the ETC Participant from an ESRD facility or related entity would result in steering a beneficiary to a specific ESRD facility or chain of ESRD facilities.

To further ensure that beneficiaries are not unduly influenced to choose a particular ESRD facility, we are also considering whether the final rule should include a requirement that, for purposes of the waiver under§ 512.397(b)(1), the content of the kidney disease patient education furnished by clinical staff cannot market a specific ESRD facility or chain of ESRD facilities to beneficiaries. However, we recognize that some forms of marketing can be quite subtle. For example, a beneficiary's treatment choices could be unduly biased if the beneficiary is made aware of the leased staff person's employment by an ESRD facility (for example, by the trainer's responses to beneficiary questions or discussion of personal experience, or even by a logo on the trainer's clothing or educational materials). Because it would be difficult for us to enforce this content restriction in many cases of subtle marketing, we do not think this restriction would sufficiently protect against improper influence of beneficiary choice with respect to the selection of an ESRD facility unless we also finalize our proposal to prohibit qualified staff from furnishing kidney disease patient education services if they are leased from or otherwise provided by an ESRD facility.

We solicit public comments on these proposed changes to § 512.397(b)(1).

3. Publication of Participant Performance

In the Specialty Care Models final rule, CMS established certain general provisions in subpart A of 42 CFR part 512 that apply to the ETC Model. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that in order to enable CMS to evaluate the Innovation Center models (defined to include the ETC Model and Radiation Oncology Model) as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we would use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models (85 FR 61124). We also stated that, consistent with section 1115A(b)(4)(B) of the Act, CMS would disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We stated that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources. We finalized these policies in 42 CFR 512.140(a).

Consistent with these provisions, we intend to publish patient de-identified results from all MYs of the ETC Model, including results from MYs that have already been completed. Specifically, for each MY, we intend to post the aggregate results for the home dialysis rate and the transplant rate for each aggregation group, as well as the individual components of each rate for the aggregation group as a whole. This would include the number of beneficiary months in home dialysis, self-dialysis, or nocturnal dialysis and the number of beneficiary months on the transplant waitlist, as well as the number of living donor transplants and, if applicable, pre-emptive living donor transplants performed. We would also identify all of the ESRD facilities or Managing Clinicians in the aggregation group for the MY. The results would be published on the ETC Model website. Given that the ETC Model includes a process for ETC Participants to request a targeted review of the calculation of the modality performance score (MPS)—which is calculated based on the various rates we intend to publish—CMS intends to publish these rates only after they have been finalized and CMS has resolved any targeted review requests timely received from ETC Participants under 42 CFR 512.390(c). We believe that the release of this information would inform the public about the cost and quality of care and about ETC Participants' performance in the ETC Model. This would supplement the annual evaluation reports that CMS is required to conduct and release to the public under section 1115A(b)(4) of the Act.

We seek comment on our intent to post this information to our website, as well as the information we intend to post and the manner and timing of the posting.

VI. Collection of Information Requirements

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 should be approved by OMB, section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2020 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 (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available median hourly wage of a Medical Records and Health Information Technician is $21.20 per hour.[372] We also calculate fringe benefit and overhead at 100 percent. We 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. We stated that 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, we stated that there is no practical alternative and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimated an hourly labor cost of $42.40 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

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 2025 that we discussed in the CY 2022 ESRD QIP final rule (86 FR 61998 through 61999) and to estimate the total information collection burden in the ESRD QIP for PY 2026. We provide the re-estimated information collection burden associated with the PY 2025 ESRD QIP and the newly estimated information collection burden associated with the PY 2026 ESRD QIP in section VII.C.3 of this proposed rule. Although we are also proposing updates for PY 2023 and PY 2024, these proposals would not affect our estimates of the annual burden associated with the program's information collection requirements, and therefore we are not updating our previously finalized information collection burdens associated with the PY 2023 or PY 2024 ESRD QIP in this proposed rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2025 and PY 2026 (OMB Control Numbers 0938–1289 and 0938–1340)

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). Although we are now using EQRS to report data that was previously reported in CROWNWeb, the data validation methodology remains the same. Under this methodology, 300 facilities are selected each 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 not proposing any changes to the EQRS data validation process, however, we are updating these burden estimates using a newly available wage estimate of a Medical Records and Health Information Technician. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $31,800 (750 hours × $42.40), or an annual total of approximately $106.00 ($31,800/300 facilities) per facility in the sample. The burden cost increase associated with these requirements would be revised in the information collection request (OMB control number 0938–1289).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is 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 policy is the time and effort necessary to submit the requested records to a CMS contractor. In this proposed rule, we are not proposing any changes to the NHSN data validation process, however, we are updating these burden estimates using a newly available wage estimate of a Medical Records and Health Information Technician. Applying our policy to reduce the number of records required from each facility participating in the NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 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 $63,600 (1,500 hours × $42.40), or a total of approximately $212 ($63,600/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements would be revised in the information collection request (OMB control number 0938–1340).

3. EQRS Reporting Requirements for PY 2023 and PY 2024 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the

[372] *https://www.bls.gov/oes/current/oes292098.htm.* Accessed on June 7, 2021.

total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS 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 EQRS, and the number of facilities submitting data to EQRS. In the CY 2021 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2023 ESRD QIP was approximately $208 million (85 FR 71475).

As discussed in section IV.B.2 of this proposed rule, we are proposing six measure suppressions that would apply for PY 2023. However, we believe that these proposals would not affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. Although we are updating the SHR and SRR clinical measure results to be expressed as rates beginning in PY 2024 in section IV.D of this proposed rule, these technical updates would not affect our estimates of the annual burden associated with the Program's information collection requirements.

4. EQRS Reporting Requirements for PY 2025 and PY 2026 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as 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 EQRS 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 EQRS, and the number of facilities submitting data to EQRS. In the CY 2022 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2025 ESRD QIP was approximately $215 million for approximately 5,085,050 total burden hours (86 FR 61999).

We are not proposing any changes in this proposed rule that would affect the burden associated with EQRS reporting requirements for PY 2025 or PY 2026. However, we have re-calculated the burden estimate for PY 2025 using updated estimates of the total number of ESRD 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 EQRS reporting. Consistent with our approach in the CY 2022 ESRD PPS final rule (86 FR 61999), in this proposed rule we are estimating that the amount of time required to submit measure data to EQRS is 2.5 minutes per element and are not using a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 229 data elements for 532,931 patients across 7,717 facilities. At 2.5 minutes per element, this yields approximately 658.94 hours per facility. Therefore, the PY 2025 burden is 5,085,050 hours (658.94 hours $\times$ 7,717 facilities). Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2025 total burden cost is approximately $215 million (5,085,050 hours $\times$ $42.40). Although the burden hours and associated burden cost in this proposed rule are the same as we previously finalized in the CY 2022 ESRD PPS final rule (86 FR 61999), we will update these numbers in the final rule if necessary. There is no net incremental burden change from PY 2025 to PY 2026 because we are not changing the reporting requirements for PY 2026.

5. Additional Reporting Requirements Beginning With PY 2025

In section IV.E.1.a of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination reporting measure beginning with the PY 2025 ESRD QIP. Facilities would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC information collection requirement (ICR) approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[373] Although the burden associated with the COVID–19 HCP Vaccination reporting measure is not accounted for under the CDC ICR 0920–1317 or 0920–0666 due to the NCVIA waiver, the estimated cost and burden information are included in section VII.D.2.b and would be accounted for by the CDC under OMB control number 0920–1317.

If you comment on these information collection, that is, reporting, recordkeeping, or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by August 29, 2022.

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD 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 several routine updates and policy changes to the ESRD PPS for CY 2023. The proposed routine updates include the CY 2023 wage index values, the wage index budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to ESRD beneficiaries.

This rule also proposes a number of changes to improve payment stability and adequacy under the ESRD PPS. As discussed in section II.B.1.a.(1) of this proposed rule, we are proposing to rebase and revise the ESRDB market basket to reflect a CY 2020 base year. We are also proposing to increase the ESRD PPS wage index floor as discussed in section II.B.1.b.(3) of this proposed rule, and to apply a permanent 5-percent cap on wage index decreases for CY 2023 and subsequent years, as discussed in section II.B.1.b.(2) of this proposed rule. Lastly, as discussed in section II.B.1.c.(4) of this proposed rule, we are proposing to change our

[373] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

methodology for calculating the FDL amount for adults in order to target more effectively ESRD PPS outlier payments that equal 1 percent of total ESRD PPS payments. We believe that each of these proposed changes would improve payment stability and adequacy under the ESRD PPS.

Furthermore, as discussed in section II.B.1.f. of this proposed rule, we are proposing to modify the definition of ''oral-only drug'' at § 413.234(a) to specify that equivalence refers to functional equivalence, in line with our current drug designation process and reliance on the ESRD PPS functional categories. We believe this proposal would improve beneficiaries' access to renal dialysis drugs, promote health equity, and advance other goals as discussed in the proposal. Lastly, we are proposing to clarify the descriptions of several existing ESRD PPS functional categories to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. We believe this proposed clarification would improve public understanding of the ESRD PPS functional categories and drug designation process.

2. AKI

This rule proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B.2 of this proposed rule, we are also proposing to apply to all AKI dialysis payments in an ESRD facility the same wage index floor and permanent 5-percent cap on wage index decreases that we are proposing to apply under the ESRD PPS. We believe that these proposed changes would improve payment stability and adequacy for AKI dialysis in ESRD facilities. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires a payment reduction of up to 2 percent for eligible facilities that do not meet or exceed the mTPS established with respect to performance standards for the ESRD QIP each year. This proposed rule proposes updates for the ESRD QIP, including the proposed suppression of several ESRD QIP measures for PY 2023 under our previously finalized measure suppression policy, a proposed update to the PY 2023 performance standards, updates regarding the SHR clinical measure and the SRR clinical measure for PY 2024, and proposed updates regarding the STrR and Hypercalcemia measures, the proposed adoption of the COVID–19 HCP Vaccination reporting measure, as well as a proposal to create a new reporting measure domain and to re-weight current measure domains, beginning in PY 2025.

4. ETC Model

As described in detail in section V of this proposed rule, we believe it is necessary to propose certain changes to the ETC Model. Under the proposed changes to the ETC Model, ETC Participants would continue to receive adjusted payments but beginning MY5, certain aspects of the ETC Model used to determine those payment adjustments would change. The proposed change to the PPA achievement scoring methodology is necessary to increase fairness and accuracy of the PPA. The proposed change to the kidney disease patient education services waiver and the discussion of our intent to disseminate participant-level model performance information to the public are necessary to support ETC Participants operating in the ETC Model.

B. Overall Impact

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

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 significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. We solicit comments on the regulatory impact analysis provided.

C. Impact Analysis

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately $320 million in payments to ESRD facilities in CY 2023, which includes the amount associated with proposed updates to the outlier thresholds, proposed payment rate update, proposed updates to the wage index, and continuation of the approved TPNIES from CY 2022.

2. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately $2 million in payments to ESRD facilities in CY 2023.

3. ESRD QIP

We estimate that the proposed updates to the ESRD QIP will result in an additional $37 million in estimated payment reductions across all facilities for PY 2025.

4. ETC Model

We estimate that the proposed changes to the ETC Model would not impact the Model's projected direct savings from payment adjustments alone. We estimate that the Model would generate $28 million in direct savings related to payment adjustments over 6.5 years.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes proposed in

this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the proposed CY 2023 ESRD PPS and AKI payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective payments to ESRD facilities would enhance the efficiency of the Medicare program. Additionally, we expect that updating ESRD PPS and AKI payments by 2.4 percent based on the proposed CY 2023 ESRD PPS market basket update less the proposed CY 2023 productivity adjustment would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this proposed rule regarding ESRD PPS and AKI rates-setting would create additional cost or burden to ESRD facilities.

b. ESRD QIP

As discussed in section IV.B.2 of this proposed rule, we are proposing measure suppressions that would apply for PY 2023. However, we believe that none of the policies that we are proposing in this proposed rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. For PY 2025 and PY 2026, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of ESRD 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 EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study), the NHSN validation study, and EQRS reporting.

In section IV.E.1.a of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination reporting measure beginning in PY 2025. Facilities would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[374]

We estimate that it would take each facility, on average, approximately 1 hour per month to collect data for the COVID–19 HCP Vaccination reporting measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe it would take an Administrative Assistant [375] between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For PY 2025 and subsequent years, facilities would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per facility and between 69,453 hours (9 hours/facility × 7,717 facilities) and 115,755 hours (15 hours/facility × 7,717 facilities) for all facilities. Each facility would incur an estimated cost of between $329.58 (9 hours × $36.62/hour) and $549.30 annually (15 hours × $36.62/hour). The estimated cost across all facilities would be between $2,543,368.86 ($329.58/facility × 7,717 facilities) and $4,238,948 ($549.30/facility × 7,717 facilities) annually. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 HCP Vaccination reporting measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into the NHSN.

We also updated the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $215 million in information collection burden, which includes the cost of complying with this rule, and an additional $37 million in estimated payment reductions across all facilities for PY 2025, for an impact of $252 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule.

For PY 2026, we estimate that the proposed revisions to the ESRD QIP would result in $215 million in information collection burden, and $37 million in estimated payment reductions across all facilities, for an impact of $252 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule.

3. Transfers

We estimate that the proposed updates to the ESRD PPS and AKI payment rate would result in a total in increase of approximately $260 million in payments to ESRD facilities in CY 2023, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $2 million in payments to ESRD facilities in CY 2023 due to the proposed updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately $260 million in transfers from the federal government to ESRD facilities due to increased Medicare program payments and approximately $60 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of 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

[374] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[375] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 29, 2022). The adjusted hourly wage rate of $36.62/hour includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 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 214 minutes (3.6 hours) for the staff to review half of this proposed rule, which is approximately 53,500 words. For each entity that reviews the rule, the estimated cost is $414.79 (3.6 hours × $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $118,629.94 ($414.79 × 286).

5. Impact Statement and Table

a. CY 2023 End-Stage Renal Disease Prospective Payment System

(1) 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 2022 to estimated payments in CY 2023. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2022 and CY 2023 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 2021 data from the Part A and Part B Common Working Files as of February 18, 2022, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2021 claims to 2022 and 2023 using various updates. The proposed updates to the ESRD PPS base rate are described in section II.B.1.d of this proposed rule. Table 25 shows the impact of the estimated CY 2023 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2022.

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TABLE 25: Impacts of the Proposed Changes in Payments to ESRD Facilities for CY 2023

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Proposed Changes to Outlier Policy (C)	Proposed change to LRS (D)	Proposed Wage Index Changes (E)	Total Percent Change[1] (F)
All Facilities	7,847	35.0	0.7%	0.0%	0.0%	3.1%
Type						
Freestanding	7,471	33.7	0.7%	0.0%	0.0%	3.1%
Hospital based	376	1.4	1.4%	0.0%	-0.1%	3.7%
Ownership Type						
Large dialysis organization	5,964	27.1	0.7%	0.0%	0.0%	3.0%
Regional chain	904	4.3	0.6%	0.2%	0.1%	3.3%
Independent	466	2.1	0.7%	0.3%	-0.1%	3.2%
Hospital based	376	1.4	1.4%	0.0%	-0.1%	3.7%
Unknown	137	0.1	0.5%	0.1%	0.3%	3.3%
Geographic Location						
Rural	1,281	5.0	0.6%	-0.6%	-0.2%	2.3%
Urban	6,566	30.0	0.7%	0.1%	0.0%	3.2%
Census Region						
East North Central	1,222	4.7	0.7%	-0.2%	-0.3%	2.7%
East South Central	618	2.4	0.7%	-0.7%	-0.3%	2.1%

Middle Atlantic	886	4.3	0.8%	0.3%	-0.2%	3.4%
Mountain	436	1.9	0.5%	-0.1%	-0.1%	2.7%
New England	201	1.2	0.6%	0.2%	-0.6%	2.6%
Pacific[2]	966	5.6	0.5%	0.9%	0.6%	4.4%
Puerto Rico and Virgin Islands	52	0.1	0.4%	-1.9%	7.1%	8.1%
South Atlantic	1,827	8.0	0.8%	-0.3%	-0.1%	2.7%
West North Central	514	1.9	0.8%	-0.3%	-0.4%	2.5%
West South Central	1,125	4.8	0.7%	-0.4%	0.2%	2.9%
Facility Size						
Less than 4,000 treatments	1,229	1.9	0.6%	-0.1%	-0.1%	2.8%
4,000 to 9,999 treatments	3,095	10.1	0.7%	-0.2%	-0.1%	2.8%
10,000 or more treatments	3,358	22.9	0.7%	0.1%	0.1%	3.3%
Unknown	165	0.2	0.6%	0.1%	0.3%	3.4%
Percentage of Pediatric Patients						
Less than 2%	7,735	34.8	0.7%	0.0%	0.0%	3.1%
Between 2% and 19%	44	0.2	0.7%	-0.2%	0.1%	2.9%
Between 20% and 49%	12	0.0	0.1%	-0.3%	-0.6%	1.6%
More than 50%	56	0.0	0.2%	0.0%	-0.3%	2.3%

[1] This column includes the impact of the proposed updates in columns (C) through (E) in Table 23, and of the proposed ESRD market basket increase factor for CY 2023 (2.8 percent), reduced by 0.4 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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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.1.c of this proposed rule is shown in column C. For CY 2023, the impact on all ESRD facilities as a result of the proposed changes to the outlier payment policy would be a 0.7 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2023 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed update to the LRS for CY 2023 of 55.2 percent. This proposed update is implemented in a budget neutral manner, so the total impact of this proposed change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. Facilities located in rural areas are estimated to experience a 0.6 percent decrease in payments, and those located in urban areas are estimated to experience a 0.1 percent increase in payments.

Column E shows the effect of the proposed updates to the wage index, as described in section II.B.1.b of this proposed rule. That is, this column reflects the update from the CY 2022 ESRD PPS wage index continuing to use the 2018 OMB delineations as finalized in the CY 2021 ESRD PPS final rule, with a basis of the FY 2023 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. This column also includes the proposed increase of the wage index floor to 0.6000 and the proposed permanent 5-percent cap on wage index decreases. 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 largest estimated increase would be 7.1 percent for facilities located in Puerto Rico and the Virgin Islands, and the largest estimated decrease would be 0.6 percent for facilities in New England.

Column F reflects the overall impact, that is, the effects of the proposed outlier policy changes, the updated wage index, and the proposed payment rate update as described in section II.B.1.d of this proposed rule. The proposed ESRD PPS payment rate update is 2.4 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2023 of 2.8 percent and the proposed productivity adjustment of 0.4 percent. We expect that overall ESRD facilities would experience a 3.1 percent increase in estimated payments in CY 2023. The categories of types of facilities in the impact table show impacts ranging from a 1.6 percent increase to an 8.1 percent

increase in their CY 2023 estimated payments.

(2) 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 2023, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2023 would be approximately $8.2 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 2.0 percent in CY 2023.

(4) 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 3.1 percent overall increase in the CY 2023 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

(5) Alternatives Considered

(i) CY 2023 Impacts: 2019–2020 Versus 2021 Claims Data

Each year CMS uses the latest available ESRD claims to update the outlier threshold, budget neutrality factor, and payment rates. Due to the COVID–19 PHE, we compared the impact of using CY 2019 or CY 2020 claims against CY 2021 claims to determine if there was any substantial difference in the results that would justify potentially deviating from our longstanding policy to use the latest available data. Analysis suggested that ESRD utilization did not change substantially during the pandemic, likely due to the patients' vulnerability and need for these services. Consequently, we are proposing to use the CY 2021 data because it does not negatively impact ESRD facilities and keeps with our longstanding policy to make updates using the latest available ESRD claims data.

(ii) Proposed Outlier Methodology Alternatives

As discussed in section II.B.1.c.(4) of this proposed rule, we are proposing a change to the methodology used to determine the outlier FDL amounts for adult beneficiaries. We also considered but did not propose maintaining the current outlier methodology or decreasing the 1.0 percent outlier target. In addition, we considered but did not propose a reconciliation process for the outlier methodology.

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

(1) 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 2022 to estimated payments in CY 2023. 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 2022 and CY 2023 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 2021 data from the Part A and Part B Common Working Files as of February 18, 2022, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2021 claims to 2022 and 2023 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 26 shows the impact of the estimated CY 2023 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 2022.

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TABLE 26: Impacts of the Proposed Changes in Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2023

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Proposed change to LRS (C)	Proposed Wage Index Changes (D)	Total Percent Change[1] (E)
All Facilities	5,308	300.9	0.0%	0.0%	2.4%
Type					
Freestanding	5,188	295.6	0.0%	0.0%	2.4%
Hospital based	120	5.3	-0.3%	0.0%	2.1%
Ownership Type					
Large dialysis organization	4,355	249.8	0.0%	0.0%	2.3%
Regional chain	584	31.6	0.1%	0.0%	2.4%
Independent	198	11.7	0.2%	-0.3%	2.4%
Hospital based[2]	120	5.3	-0.3%	0.0%	2.1%
Unknown	51	2.6	0.1%	0.1%	2.6%
Geographic Location					
Rural	904	49.0	-0.6%	-0.2%	1.6%
Urban	4,404	251.9	0.1%	0.0%	2.5%
Census Region					
East North Central	882	53.1	-0.2%	-0.3%	1.8%
East South Central	414	22.5	-0.7%	-0.4%	1.3%
Middle Atlantic	551	32.3	0.2%	-0.1%	2.6%
Mountain	304	18.4	0.0%	0.1%	2.5%
New England	137	7.3	0.2%	-0.6%	2.0%
Pacific[3]	673	46.1	0.8%	0.6%	3.9%
Puerto Rico and Virgin Islands	1	0.0	-1.9%	7.6%	8.0%
South Atlantic	1,290	71.9	-0.3%	-0.2%	1.9%
West North Central	340	15.1	-0.3%	-0.3%	1.8%
West South Central	716	34.3	-0.4%	0.1%	2.1%
Facility Size					
Less than 4,000 treatments	611	24.9	-0.1%	-0.1%	2.2%
4,000 to 9,999 treatments	2,124	108.7	-0.2%	-0.2%	2.0%
10,000 or more treatments	2,514	163.8	0.1%	0.1%	2.6%
Unknown	59	3.5	0.1%	-0.1%	2.4%
Percentage of Pediatric Patients					
Less than 2%	5,308	300.9	0.0%	0.0%	2.4%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	0	0.0	0.0%	0.0%	0.0%

[1] This column includes the impact of the updates in columns (C) through (E) in Table 24, and of the proposed ESRD market basket increase factor for CY 2023 (2.8 percent), reduced by 0.4 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.
[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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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 update to the LRS for CY 2023 of 55.2 percent. Column D shows the effect of the proposed CY 2023 wage indices, including the proposed increase to the wage index floor and the proposed 5-percent cap on wage index decreases.

Column E shows the overall impact, that is, the effects of the proposed LRS, proposed wage index updates, and the proposed payment rate update of 2.4 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2023 of 2.8 percent and the proposed productivity adjustment of 0.4 percent. We expect that overall ESRD facilities would experience a 2.4 percent increase in estimated payments in CY 2023. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 8.0 percent in their CY 2023 estimated payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this proposed change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $80 million would be paid to ESRD facilities in CY 2023 as a result of patients with AKI 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.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) 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 is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

c. ESRD QIP

(1) Effects of the PY 2023 and PY 2024 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD facility services provided to beneficiaries. The general methodology that we use to determine a facility's TPS is described in our regulations at 42 CFR 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2023 and PY 2024 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2023 and CY 2024, respectively, as codified in our regulations at 42 CFR 413.177.

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2025 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2025, as codified in our regulations at 42 CFR 413.177.

For the PY 2023 ESRD QIP, we estimate that, of the 7,768 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 11.27 percent or 875 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 2021 ESRD PPS final rule (85 FR 71479 through 71481). If our proposals are finalized as proposed, the total estimated payment reductions for all the 875 facilities expected to receive a payment reduction in PY 2023 would be approximately $9,853,321.90. Facilities that do not receive a TPS do not receive a payment reduction.

Table 27 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 27: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	6,622	85.25%
0.5%	267	3.44%
1.0%	208	2.68%
1.5%	222	2.86%
2.0%	178	2.29%

*271 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 EQRS and Medicare claims, excluding the measures that we are proposing to suppress for PY 2023 as discussed in section IV.B.2 of this proposed rule. Payment reduction estimates are calculated using the most recent data available (specified in Table 28) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 28.

TABLE 28: 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*	N/A	N/A
SRR*	N/A	N/A
SHR*	N/A	N/A
PPPW*	N/A	N/A
Kt/V Dialysis Adequacy Comprehensive*	N/A	N/A
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter*	N/A	N/A
STrR	Jan 2018-Dec 2018	Jan 2019-Dec 2019

*Note: We are proposing to suppress the ICH CAHPS measure, the SRR clinical measure, the SHR clinical measure, the PPPW clinical measure, the Kt/V Dialysis Adequacy Comprehensive measure, and the Long-Term Catheter Rate measure for PY 2023, as discussed in section IV.B.2 of this proposed rule.

For all measures except the six measures we are proposing to suppress in IV.B.2 of this proposed rule, as well as the STrR measure, measures with less than 11 patients for a facility were not included in that 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 were consistent with the proposed polices outlined in sections IV.B and IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2019 and CY 2020 for MedRec. 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 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

(2) Effects of the PY 2025 ESRD QIP on ESRD Facilities

For the PY 2025 ESRD QIP, we estimate that, of the 7,717 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41 percent or 3,171 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2025. We are presenting an estimate for the PY 2025 ESRD QIP to update the estimated impact that was provided in the CY 2022 ESRD PPS final rule (86 FR 62008 through 62011). If our proposals are finalized as proposed, the total estimated payment reductions for all the 3,171 facilities expected to receive a

payment reduction in PY 2025 would be approximately $37,167,805.51. Facilities that do not receive a TPS do not receive a payment reduction.

Table 29 shows the overall estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP.

TABLE 29: Estimated Distribution of PY 2025 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4,214	57.06%
0.5%	1,769	23.95%
1.0%	999	13.53%
1.5%	332	4.50%
2.0%	71	0.96%

*332 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2025, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 28) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 30.

TABLE 30: Data Used to Estimate PY 2025 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 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2018-Dec 2018	Jan 2019-Dec 2019

*Note: PPPW score is based on achievement score only.

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, 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, which we are proposing to convert to a clinical measure beginning in PY 2025 in section IV.E.1.b of this proposed rule, 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 were consistent with the proposed polices outlined in section IV.E of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2019 and CY 2020 for MedRec. 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 2025 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 31 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2025. 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

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 2025 ESRD QIP, the actual impact of the PY 2025 ESRD QIP may vary significantly from the values provided here.

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TABLE 31: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025

	Number of Facilities	Number of Treatments 2019 (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	7,717	43.4	7,385	3,171	-0.34%
Facility Type:					
Freestanding	7,339	41.7	7,039	3,007	-0.33%
Hospital-based	378	1.7	346	164	-0.43%
Ownership Type:					
Large Dialysis	5,886	33.6	5,718	2,304	-0.30%
Regional Chain	887	5.3	852	407	-0.41%
Independent	515	2.8	467	296	-0.62%
Hospital-based (non-chain)	378	1.7	346	164	-0.43%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,570	2,711	-0.31%
Small Entities[1]	893	4.5	813	460	-0.54%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,242	421	-0.26%
2) No	6,449	37.1	6,143	2,750	-0.35%
Census Region:					
Northeast	1,060	6.4	1,001	426	-0.33%
Midwest	1,716	7.9	1,666	751	-0.36%
South	3,506	20.1	3,368	1,623	-0.38%
West	1,374	8.5	1,291	327	-0.17%
US Territories[2]	61	0.4	59	44	-0.68%
Census Division:					
Unknown	9	0.1	8	4	-0.43%
East North Central	1,213	5.6	1,172	583	-0.41%
East South Central	609	3.2	593	272	-0.35%
Middle Atlantic	859	5.1	808	366	-0.35%
Mountain	428	2.3	405	96	-0.17%
New England	201	1.3	193	60	-0.23%
Pacific	946	6.2	886	231	-0.17%
South Atlantic	1,794	10.4	1,707	821	-0.39%
West North Central	503	2.3	494	168	-0.23%
West South Central	1,103	6.5	1,068	530	-0.40%
US Territories[2]	52	0.3	51	40	-0.72%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,096	338	-0.26%
4,000-9,999 treatments	2,905	11.9	2,904	1,147	-0.31%
Over 10,000 treatments	3,384	28.9	3,383	1,684	-0.38%
Unknown	180	0.2	2	2	-0.75%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(3) Effects of the PY 2026 ESRD QIP on ESRD Facilities

For the PY 2026 ESRD QIP, we estimate that, of the 7,717 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41 percent or 3,171 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. The total payment reductions for all the 3,171 facilities expected to receive a payment reduction is approximately $37,167,805.51. Facilities that do not receive a TPS do not receive a payment reduction.

Table 32 shows the overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 32: Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4,214	57.06%
0.5%	1,769	23.95%
1.0%	999	13.53%
1.5%	332	4.50%
2.0%	71	0.96%

*Note: 332 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2026, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 32) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 33.

TABLE 33: Data Used to Estimate PY 2026 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 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2018-Dec 2018	Jan 2019-Dec 2019

*Note: PPPW score is based on achievement score only

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, 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, which we are proposing to convert to a clinical measure beginning in PY 2025 in section IV.E.1.b of this proposed rule, 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 policies outlined in section IV.F of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2019 and CY 2020 for MedRec. 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 2026 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 34 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. 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 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 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

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TABLE 34: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (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	7,717	43.4	7,385	3,171	-0.34%
Facility Type:					
Freestanding	7,339	41.7	7,039	3,007	-0.33%
Hospital-based	378	1.7	346	164	-0.43%
Ownership Type:					
Large Dialysis	5,886	33.6	5,718	2,304	-0.30%
Regional Chain	887	5.3	852	407	-0.41%
Independent	515	2.8	467	296	-0.62%
Hospital-based (non-chain)	378	1.7	346	164	-0.43%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,570	2,711	-0.31%
Small Entities[1]	893	4.5	813	460	-0.54%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,242	421	-0.26%
2) No	6,449	37.1	6,143	2,750	-0.35%
Census Region:					
Northeast	1,060	6.4	1,001	426	-0.33%
Midwest	1,716	7.9	1,666	751	-0.36%
South	3,506	20.1	3,368	1,623	-0.38%
West	1,374	8.5	1,291	327	-0.17%
US Territories[2]	61	0.4	59	44	-0.68%
Census Division:					
Unknown	9	0.1	8	4	-0.43%
East North Central	1,213	5.6	1,172	583	-0.41%
East South Central	609	3.2	593	272	-0.35%
Middle Atlantic	859	5.1	808	366	-0.35%
Mountain	428	2.3	405	96	-0.17%
New England	201	1.3	193	60	-0.23%
Pacific	946	6.2	886	231	-0.17%
South Atlantic	1,794	10.4	1,707	821	-0.39%
West North Central	503	2.3	494	168	-0.23%
West South Central	1,103	6.5	1,068	530	-0.40%
US Territories[2]	52	0.3	51	40	-0.72%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,096	338	-0.26%
4,000-9,999 treatments	2,905	11.9	2,904	1,147	-0.31%
Over 10,000 treatments	3,384	28.9	3,383	1,684	-0.38%
Unknown	180	0.2	2	2	-0.75%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD 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 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 Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2026, we estimate that the ESRD QIP would contribute approximately $37,167,805.51 in Medicare savings. For comparison, Table 35 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2026.

TABLE 35: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2026

Payment Year	Estimated Payment Reductions
PY 2026	$37,167,805.51
PY 2025	$37,167,805.51
PY 2024	$17,104,030.59 (86 FR 62011)
PY 2023	$9,853,321.90
PY 2022	$0[376] (86 FR 62011)
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)

(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD 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 would 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.

(7) Alternatives Considered

In section IV.B.2 of this proposed rule, we are proposing to suppress six measures for PY 2023 due to the impacts of the COVID–19 PHE on CY 2021 data. We considered not suppressing these six measures for PY 2023. However, we concluded that measure suppression was appropriate under our previously finalized measure suppression policy due to the impact of the COVID–19 PHE on these PY 2023 ESRD QIP measures. This approach would help to ensure that a facility would not be penalized for performance on measures which have been impacted by extraordinary circumstances beyond the facility's control.

d. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114) and the CY 2022 ESRD PPS final rule (86 FR 61874), for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C.

The changes proposed in this proposed rule (discussed in detail in section V.B of this proposed rule) would impact model payment adjustments for PPA Period 5, starting July 1, 2024. The proposed change that is most likely to affect the impact estimate for the ETC Model is the proposal to add a parameter to the PPA achievement scoring methodology such that an ETC Participant's aggregation group must have a positive home dialysis rate or transplant rate to receive an achievement score for that rate, as described in section V.B.1 of this proposed rule. We do not anticipate that the proposal to clarify the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers, described in section V.B.2 of this proposed rule, would affect the impact estimate for the ETC Model.

The ETC Model is not a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they would in the absence of the ETC Model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the proposed changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the proposed changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

For the modeling exercise used to estimate changes in payment to providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method to simulate identification of ETC Participants (including aggregation group construction), beneficiary attribution (and exclusions), calculation

[376] In the CY 2022 ESRD PPS final rule, we finalized our proposed special scoring methodology and payment policy for PY 2022 (86 FR 61918 through 61919). Under this policy, we will not apply any payment reductions to ESRD facilities for PY 2022.

of home dialysis rates and transplant rates, calculation of achievement benchmarks, and calculation of improvement scores. For a detailed description of this methodology, see the detailed economic analysis included in the CY 2022 ESRD PPS final rule (86 FR 62012 through 62014).

Beginning for MY5 and beyond, the PPA achievement scoring methodology included one modification. Specifically, achievement scores were only awarded for the home dialysis rate or the transplant rate to ETC Participants in aggregation groups with a home dialysis rate or transplant rate greater than zero, respectively, in accordance with the proposed change described in section V.B.1 of this proposed rule. To clarify, no changes to the achievement scoring methodology were made to MY1 through MY4. For a detailed description of the methodology for simulating achievement scoring methodology, see the CY 2022 ESRD PPS final rule (86 FR 60213 through 60214).

No changes were made to the payment structure for the HDPA calculation, as no changes were proposed. Similarly, no changes were made to the kidney disease patient education services utilization and cost calculations, as the proposed change does not impact expected utilization. For a detailed description of this methodology, see the detailed economic analysis included in the CY 2022 ESRD PPS final rule (86 FR 62014).

(3) Medicare Estimate—Primary Specification, Assume Proposed Achievement Scoring Update

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TABLE 36: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

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Table 36 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program will save a net total of $43 million from the PPA and HDPA between January 1, 2021 and June 30, 2027 less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was

also estimated to be $28 million in savings (86 FR 62014 through 62016).

In Table 36, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

As was the case in the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 61874), the projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary FFS effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The changes proposed in this proposed rule would not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes proposed in this proposed rule would not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) or the CY 2022 ESRD PPS final rule (85 FR 62017).

(6) Effects on Medicare Beneficiaries

The changes proposed in this proposed rule would not impact the findings reported for the effects of ETC Model on Medicare beneficiaries regarding the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for Medicare beneficiaries.

As previously noted in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 62017), we continue to anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same for most beneficiaries under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the ETC Model and hold beneficiaries harmless from any effect of these payment adjustments on cost sharing.

In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis, or nocturnal in-center dialysis, as opposed to in-center dialysis. As discussed in the Specialty Care Models final rule, studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; as well as better overall, physical, and psychological health in comparison to other dialysis options (85 FR 61264 through 61270).

(7) Alternatives Considered

Throughout this proposed rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and rationale for each of our policies

This proposed rule addresses a model specific to ESRD. It provides descriptions of the requirements that we would waive, identifies the performance metrics and payment adjustments proposed to be tested, and presents rationales for our proposals, and where relevant, alternatives considered. We carefully considered the alternatives to this proposed rule. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to the Specialty Care Models final rule (85 FR 61114) and the CY 2022 ESRD PPS final rule (86 FR 61874), respectively, for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy preceding the limited modifications proposed here.

E. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 37 showing the classification of the impact associated with the provisions of this proposed rule.

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TABLE 37: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2023)	
Category	**Transfers**
Annualized Monetized Transfers	$260 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$60 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2023	
Category	Transfers
Annualized Monetized Transfers	-$9 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2025	
Category	Transfers
Annualized Monetized Transfers	-$37 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-$37 million
From Whom to Whom	Federal government to ESRD providers
ETC Model for July 1, 2022 through June 30, 2027	
Category	**Transfers**
Annualized Monetized Transfers	$0.03 million
From Whom to Whom	Federal government to ESRD facilities and Managing Clinicians

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F. Regulatory Flexibility Act Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. 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. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards [377], an ESRD facility is classified as a small business if it has total revenues of less than $41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $9.3 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 466 facilities that are independent and 376 facilities that are hospital-based, as shown in the ownership category in Table 25, to be small businesses. These facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 817 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 376 nonprofit ESRD facilities that are also considered small businesses, there are 1,283 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 3.7 percent increase in payments for CY 2023. An independent facility (as defined by ownership type) is estimated to receive a 3.2 percent increase in payments for CY 2023. As shown in Table 25, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare payments by approximately 3.1 percent.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $80 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 3,171 ESRD facilities expected to receive a payment reduction as a result

[377] More information available at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as North American Industry Classification System (NAICS) code 621492 with a size standard of $41.5 million).

of their performance on the PY 2025 ESRD QIP, 460 are ESRD small entity facilities. We present these findings in Table 29 (''Estimated Distribution of PY 2025 ESRD QIP Payment Reductions'') and Table 31 (''Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025'').

For the ETC Model, this proposed rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model, pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business. The greater majority of ESRD facilities are not small entities, as they are owned, partially or entirely, by entities that do not meet the SBA definition of small entities. Under the ETC Model, the HDPA is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA, which includes both positive and negative adjustments on payments for dialysis and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same Tax Identification Number (TIN) within a Selected Geographic Area. Taken together, the low volume threshold exclusions and aggregation policies, coupled with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaires; we have determined that the provisions of the proposed rule for the ETC Model would not have a significant impact on spending for a substantial number of small entities.

The HDPA is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA, which includes both positive and negative adjustments on payments for dialysis and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same Tax Identification Number (TIN) within a Selected Geographic Area, which increases the statistical liability of the home dialysis rate and the transplant rate for ETC Participants in the aggregation group. Taken together, the low volume threshold exclusions and aggregation policies, coupled with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaires; we have determined that the provisions of the proposed rule would not have a significant impact on spending for 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. As a result, since the overall estimated impact of these proposed updates is a net increase of greater than 3 percent in revenue across almost all categories of ESRD facility, the Secretary has determined that this proposed rule will have a significant positive revenue impact on a substantial number of ESRD facilities identified as small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. 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 will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities will experience an estimated 2.8 percent increase in payments. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. 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 2022, that threshold is approximately $165 million. This proposed rule does not mandate any requirements for state, local, or tribal governments, in the aggregate, or by the private sector of more than $165 million in any 1 year. 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.

H. 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 will not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

VIII. 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.

IX. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on the CMS website under the regulation number, CMS–1768–P at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* In addition to the Addenda, limited data set files are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.* Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov.*

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 13, 2022.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, 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 set forth below:

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 413.178 is amended by revising paragraphs (a)(8) and (d)(2) and adding paragraph (i) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

* * * * *

(d) * * *

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to each of payment year 2023 and payment year 2024 is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2019 for purposes of calculating the improvement threshold. The baseline period that applies to payment year 2025 is calendar year 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold, and the performance period that applies to payment year 2025 is calendar year 2023. Beginning with payment year 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

* * * * *

(i) *Special Rules for Payment Year 2023.* (1) CMS will calculate a measure rate for, but will not score facility performance on or include in the TPS for any facility under paragraph (e) of this section, the following measures: Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, Long-Term Catheter Rate clinical measure, ICH CAHPS clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy clinical measure.

(2) The mTPS for payment year 2023 is the total performance score that an ESRD facility would receive if, during the calendar year 2019 baseline period, it performed at the 50th percentile of national ESRD facility performance on Standardized Fistula Rate clinical measure, Hypercalcemia clinical measure, NHSN Blood Stream Infection (BSI) clinical measure, and the median of national ESRD facility performance on Clinical Depression Screening and Follow-Up reporting measure, Standardized Transfusion Ratio (STrR) reporting measure, Ultrafiltration Rate reporting measure, NHSN Dialysis Event reporting measure, and Medication Reconciliation (MedRec) reporting measure.

■ 3. Section 413.231 is amended by adding paragraphs (c) and (d) to read as follows:

§ 413.231 Adjustment for wages.

* * * * *

(c) Beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to that ESRD facility in the prior calendar year.

(d) Beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

§ 413.234 [Amended]

■ 4. In § 413.234, amend paragraph (a) by adding the word ''functional'' before the word ''equivalent'' in the definition of ''Oral-only drug''.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 5. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 6. Section 512.370 is amended by revising paragraph (b) introductory text and adding paragraph (b)(3) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement Scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY10, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY10, the ETC Participant's achievement score is subject to the restriction described in paragraph (b)(3) of this section.

* * * * *

(3) For MY5 through MY10, CMS will assign an achievement score to an ETC Participant for the home dialysis rate or the transplant rate only if the ETC Participant's aggregation group has a home dialysis rate or a transplant rate greater than zero for the MY.

* * * * *

■ 7. Section 512.397 is amended by revising paragraph (b)(1) to read as follows:

§ 512.397 ETC Model Medicare program waivers and additional flexibilities.

* * * * *

(b) * * *

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff (as defined at § 512.310) under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The kidney disease patient education services may be

furnished only by qualified staff (as defined at § 512.310). Beginning MY5, only clinical staff that are not leased from or otherwise provided by an ESRD facility or related entity may furnish kidney disease patient education services pursuant to the waiver described in this section.

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Dated: June 17, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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