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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS-1768-F]

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

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

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2023. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule updates requirements for the ESRD Quality Incentive Program and finalizes changes to the ESRD Treatment Choices Model.

DATES: These regulations are effective on January 1, 2023, except for the amendments to 42 CFR 413.234, which are effective January 1, 2025.

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 acute kidney injury (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 Quality Incentive Program (QIP).

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

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), 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 rule updates 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 rule updates 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 final rule finalizes 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, PY 2025, and PY 2026.

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." In this rule, we finalize 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 final 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 updating the ESRDB market basket to a 2020 base year, reflecting the most recent and complete set of Medicare Cost Report (MCR) data as well as other publicly available data. In addition, we are updating the labor-related share of the ESRD PPS base rate to reflect the 2020 labor-related cost share weights designated in the ESRDB market basket.

- Update to the ESRD PPS base rate for CY 2023: The final CY 2023 ESRD PPS base rate is $265.57. This amount reflects the application of the wage index budget-neutrality adjustment factor (0.999730) and a productivity-adjusted market basket increase of 3.0 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $265.57 (($257.90 × 0.999730) × 1.030 = $265.57).

- 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 updating the wage index values based on the latest available data.

- Permanent cap on wage index decreases: For CY 2023 and subsequent years, we are establishing a permanent policy to apply a 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 raising 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 modifying the methodology for calculating the fixed-dollar loss (FDL) amounts for adult patients.

- Annual update to the outlier policy: We are updating the outlier policy based on the most current data and our refinement to the outlier policy. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2023 using the latest available CY 2021 claims data. We are updating the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2021 claims data, and calculating the FDL amount for adult patients using the latest available claims data from CY 2019, CY 2020, and CY 2021, in accordance with the methodology discussed in section II.B.1.c.(4) of this final rule. For pediatric beneficiaries, the final FDL amount will decrease from $26.02 to $23.29, and the final MAP amount will decrease from $27.15 to $25.59, as compared to CY 2022 values. For adult beneficiaries, the final FDL amount will decrease from $75.39 to $73.19, and the final MAP amount will decrease from $42.75 to $39.62. The 1.0 percent target for outlier payments was not achieved in CY 2021. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent.

- Definition of an oral-only drug: Beginning January 1, 2025, we will include the word functional in the definition of oral-only drug at 42 CFR 413.234(a). Specifically, under the final definition, an oral-only drug will 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 final CY 2023 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $9.79. This offset amount reflects the application of the productivity-adjusted market basket increase of 3.0 percent ($9.50 × 1.030 = $9.79).

- TPNIES applications received for CY 2023: In this final rule, we announce our determinations on the three TPNIES applications under consideration for the TPNIES for CY 2023 payment.

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

We are updating the AKI payment rate for CY 2023. The final CY 2023 payment rate is $265.57, which is the same as the base rate finalized under the ESRD PPS for CY 2023.

3. ESRD QIP

We are finalizing our proposals to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, Long-Term Catheter Rate clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and 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 suppressing the Standardized Fistula Rate clinical measure for PY 2023 under our previously finalized measure suppression policy because we have determined that the

circumstances caused by the COVID-19 PHE have also significantly affected the Standardized Fistula Rate clinical measure and resulting performance score. Additionally, we are finalizing that we will calculate the minimum Total Performance Score (mTPS) for PY 2023 based on the seven measures that are not suppressed. We are also finalizing our proposal 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. We are finalizing our proposal to add the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure to the ESRD QIP measure set beginning with the PY 2025 ESRD QIP. We are also finalizing our proposal to convert the Standardized Transfusion Ratio (STrR) reporting measure to a clinical measure beginning with PY 2025, and are further finalizing our proposal to express this measure as a rate to align with the technical updates to also express the SHR and SRR clinical measure results as rates. In addition, we are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning with PY 2025. Furthermore, we are finalizing our proposal to create a new Reporting Measure domain and to re-weight remaining measure domains beginning with PY 2025.

This final rule also includes a summary of public comments received in response to requests for information that appeared in the CY 2023 ESRD PPS proposed rule. In those requests for information, we solicited feedback 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 in the ESRD QIP.

4. ETC Model

In this final rule, we are updating the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY5) of the ETC Model, which begins

January 1, 2023. We are also clarifying 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 final rule, we set forth a detailed analysis of the impacts that the finalized changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VII.D.5.a of this final 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 3.1 percent increase in payments compared with freestanding facilities with an estimated 3.0 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $300 million in CY 2023 compared to CY 2022. This reflects a $300 million increase from the payment rate update, approximately $2.5 million in estimated TPNIES payment amounts and approximately $2.3 million in estimated TDAPA payment amounts, as further described in the next paragraph. Because of the projected 3.1 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

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. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products and § 413.236 to establish the

TPNIES, a transitional add-on payment adjustment for new and innovative equipment and supplies, which are not budget neutral.

As discussed in section II.D. of this final rule, the TPNIES payment period for the Tablo® System will continue in CY 2023. We estimate that the TPNIES payment amounts for the Tablo® System in CY 2023 would be approximately $2.5 million, of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts. As discussed in section II.E. of this final rule, the TDAPA payment period for KORSUVA™ (difelikefalin) will continue in CY 2023. We estimate that the overall TDAPA payment amounts in CY 2023 would be approximately $2.3 million, of which, approximately $468,000 would be attributed to beneficiary coinsurance amounts.

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

The impact table in section VII.D.5.b of this final 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 2.9 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.8 percent increase in payments compared with freestanding ESRD facilities with an estimated 2.9 percent increase. The overall impact reflects the effects of the final update to the labor-related share, final CY 2023 wage index, final permanent cap on wage index decreases, final increase to the wage index floor, and the final payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the final CY 2023 ESRD PPS base rate, will increase by $2 million in CY 2023 compared to CY 2022.

3. Impacts of the ESRD QIP

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 (85 FR 71400). 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. In the CY 2023 ESRD PPS proposed rule, we estimated that the overall economic impact of the PY 2023 ESRD QIP would be approximately $218 million (87 FR 38467). In that proposed rule, we estimated that the $218 million figure for PY 2023 included costs associated with the collection of information requirements and recalculated estimated payment reductions based on the six measures we proposed to suppress for PY 2023. However, as a result of the policies impacting the PY 2023 ESRD QIP that we are finalizing in this final rule, including the additional suppression of the Standardized Fistula Rate clinical measure, we are modifying our previous estimate. We now estimate that the overall economic impact of the PY 2023 ESRD QIP will be approximately $213.5 million. The $213.5 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate will be approximately $208 million, and recalculated estimated payment reductions of approximately $5.5 million across all facilities based on the seven measures we are finalizing for suppression 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 will not impact our previously estimated economic impact for the PY 2024 ESRD QIP.

In the CY 2023 ESRD PPS proposed rule, we estimated 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 the proposed rule (87 FR 38467). The $252 million figure for PY 2025 included costs associated with the collection of information requirements, which we estimated would be approximately $215 million, and $37 million in estimated payment reductions across all facilities. In this final rule, we continue to estimate that the overall economic impact of the PY 2025 ESRD QIP will be approximately $252 million as a result of the policies we have previously finalized and the

proposals we are finalizing in this final rule. However, we have updated our estimated costs associated with collection of information requirements and payment reductions across all facilities. The $252 million figure for PY 2025 includes costs associated with the collection of information requirements, which we estimate would be approximately $220 million, and $32 million in estimated payment reductions across all facilities. We are also updating our 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 $220 million, and $32 million in estimated payment reductions across all facilities.

4. Impacts of the Final Changes to the ETC Model

The impact estimate in section VII.D.5.d of this final 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 changes in this final rule. We estimate that the ETC Model will result in $28 million in net savings over the 6.5 year duration of the ETC Model. We also estimate that the changes in this final rule will produce no change in net savings for the ETC Model.

II. Calendar Year (CY) 2023 End Stage Renal Disease (ESRD) Prospective Payment System (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, under 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 provides 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, Public Comments, and Responses to the Comments on the CY 2023 ESRD PPS

The proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (87 FR 38464 through 38586), referred to as the ''CY 2023 ESRD PPS proposed rule,'' appeared in the June 28, 2022 version of the **Federal Register**, with a comment period that ended on August 22, 2022. In that proposed rule, we proposed to make a number of annual updates for CY 2023, including updates to the ESRD PPS base rate, wage index, outlier policy, and the TPNIES offset amount. We also proposed several policy changes, including increasing the wage index floor, establishing a permanent cap on wage index decreases, modifying the outlier methodology, changing the definition of oral-only drug, and revising the descriptions of several ESRD PPS functional categories. The proposed rule included 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. In addition, the rule included a request 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.

We received 291 public comments on our proposals, including comments from kidney and dialysis organizations, such as large dialysis organizations (LDOs), small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and a dialysis coalition. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association, a professional association, and alliances for kidney care and home dialysis stakeholders; drug and

device manufacturers; health care systems; a health solutions company; and the Medicare Payment Advisory Commission (MedPAC).

We received several comments related to issues that we either did not discuss in the CY 2023 ESRD PPS proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes. These include, for example, concerns about infections, comments on comorbidities that should or should not be considered for payment adjustments, suggestions for changes to payments for drugs and biological products, and suggestions for additional screenings for Medicare beneficiaries to detect kidney disease earlier. In addition, we received several comments regarding the TDAPA and TPNIES payment adjustments and length of the payment period. We also received comments regarding the TPNIES application process, implementation challenges from the CY 2022 TPNIES approval for the Tablo® System, and requests to amend the ESRD facility cost report and align Medicare Advantage plans with the ESRD PPS. While we are not providing detailed responses to those comments in this final rule because they are either out of scope of the proposed rule or concern topics for which we did not propose changes, we thank the commenters for their input and will potentially consider the recommendations in future rulemaking.

We received various comments requesting changes to Medicare payments for home dialysis. Some of these suggestions were to increase payments for home dialysis training, to increase the number of training sessions for home dialysis, to increase payments for home dialysis treatments, and to allow clinics to bill for telemedicine related to home dialysis. We thank the commenters for their recommendations regarding home dialysis; however, these comments are out of scope given that we did not propose to make any changes to the Medicare payment for home dialysis. Nevertheless, we will review and assess the feasibility of the commenters' recommendations and, if warranted, consider proposing changes to our policies in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2023 ESRD PPS.

1. CY 2023 ESRD PPS Update

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

(1) 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 proposed 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. In the CY 2023 ESRD PPS proposed rule (87 FR 38468 through 38480), we proposed to use 2020 as the base year for the rebased ESRDB market basket cost weights. The cost weights for this ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2020 (that is, the average index level for CY 2020 is equal to 100). The major source data for the ESRDB market basket is the 2020 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 proposed 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 methodology in section II.B.1.a.(1)(b) of this final 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 the CY 2023 ESRD PPS proposed rule, we proposed 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 proposed 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 proposed to use CY 2020 as the new base year because 2020 is the most recent year for which relatively complete MCR data were 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 Public Health Emergency (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. We explained that 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 proposed 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 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 divided 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 applied 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 included a total of 21 detailed cost categories for the 2020-based ESRDB market basket, whereas the 2016-based ESRDB market basket had 20 detailed cost categories. A detailed discussion of the provisions is provided in section II.B.1.a.(1)(b) of this final 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 payable 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.

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

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

Cost Category	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 2020-based ESRDB market basket, the Housekeeping and Operations cost category is split into two detailed cost categories: Housekeeping and Operations & Maintenance.

We proposed 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 the CY 2023 ESRD PPS proposed rule.

Wages and Salaries

The Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 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 derived 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 derived 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 was to include Contract Labor costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid

double counting of these expenses we proposed to move the estimated cost weight for the contract labor costs from the Administrative and General category (where we believed the majority of the contract labor costs would be reported) to the Wages and Salaries category. We used 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 cost weight for Wages and Salaries increased to 36.5 percent when contract labor wages were added. The calculation of the 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: The 2020 and 2016 ESRD Wages and Salaries Cost Weight Determination

Components	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.

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 was to include contract labor benefit costs. Once again, we noted, 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 discussed 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 increased to 9.5 percent when contract labor benefits were 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: The 2020 and 2016 ESRD Employee Benefits Cost Weight Determination

Components	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 included 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 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 an ESRDB market basket weight for Pharmaceuticals of 10.1 percent. ESA expenditures accounted

for 6.0 percentage points of the 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 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 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 was 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 2020-based ESRDB market basket weight for Laboratory Services was 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 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 proposed 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 was 3.7 percent.

Capital

We developed a market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. 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 propose Capital cost weights. To calculate the Capital-related Buildings and Fixtures cost weight we summed 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 stated that 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 were 9.4 and 4.4 percent, respectively.

Administrative & General

We proposed to compute 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 proposed Administrative and General cost weight was 13.7 percent.

We proposed 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 were 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.

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

2020 Cost Category	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

2020 Cost Category	2020 Cost Weights (percent)	2016 Cost Weights (percent)
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.

We received several comments regarding the proposed methodology for deriving the detailed cost weights of the 2020-based ESRDB market basket. The comments and our responses are set forth below.

Comment: Many commenters, including LDOs, a coalition of dialysis organizations, and a professional association supported the proposal to rebase and revise the ESRDB market basket base year to 2020. These commenters agreed that the data from 2016 no longer reflect the current mix of goods and services for providing ESRD care, and some also expressed agreement with the proposed major cost categories and weights as well as the disaggregation of the Administrative & General cost category. While many commenters supported the proposed rebased market basket, several commenters stated that the 2020 revised cost weights do not adequately capture the trends in the health care labor market that have continued into 2022, and that the proposed 2020 cost weights, particularly for labor and related costs, are likely underrepresented as a portion of the market basket. These commenters requested that CMS continue to monitor the effects of the COVID-19 PHE on freestanding ESRD facilities' costs moving forward and consider rebasing the ESRDB market basket more frequently (than every four years) if these trends change and the cost category weights no longer accurately represent freestanding ESRD facilities' costs.

Response: We appreciate the commenters' support for rebasing and revising the ESRDB market basket to a 2020 base year. We also understand the commenters' concerns that the data from 2020 do not necessarily reflect the current relative cost share weights that ESRD facilities may be experiencing in 2022. However, the 2020 data reflect the latest available data available

to estimate the ESRDB market basket cost share weights at the time of the CY 2023 ESRD PPS proposed rule. We will continue to monitor the cost share weights for potential effects of the COVID-19 PHE on freestanding ESRD facilities' costs and, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly.

Comment: MedPAC requested that CMS's rebasing of the ESRDB market basket should reflect the findings from the agency's most recent audit of freestanding ESRD facilities, which found that cost reports have included costs that are not allowable under Medicare.

Response: We understand MedPAC's concerns regarding the 2018 audited cost report data[1]; however, we do not agree that the results of the audited data can be directly utilized for determining the ESRDB market basket cost weights in the 2020 cost report data. Although the audited cost report data identified potential areas where cost levels were misreported by some facilities, we do not believe that slightly different cost levels will result in substantial variation to the relative cost share weights derived from the unaudited data, since the cost weights are based on relative shares of the total. Additionally, the weights are derived from all facilities and, therefore, for an audited report to impact the overall market basket cost shares, the misreporting will have to be prevalent across a significant percentage of facilities. Finally, the audit was performed on a sample of cost reports for 2018 and we proposed to use data from 2020 cost reports; any inaccuracies in the 2018 data do not necessarily mean that 2020 data will be impacted in the same way.

Final Rule Action: After consideration of the public comments we received, we are finalizing the methodology for deriving the detailed cost weights of the 2020-based ESRDB market basket as proposed without modification.

[1] Details on the audit process and findings, as well as adjustments for unallowable costs based on its findings, can be found in the CY 2022 ESRD PPS proposed rule (86 FR 36322).

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

After developing the cost weights for the 2020-based ESRDB market basket, we proposed 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 price proxies on BLS data and grouped 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, as stated in the CY 2023 ESRD PPS proposed rule, 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. As stated in the CY 2023 ESRD PPS proposed rule, 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 meet these criteria. Therefore, as stated in the CY 2023 ESRD PPS proposed rule, we believe that they continue to be the best measure of price changes for the cost categories to which they will be applied.

Table 7 lists all proposed price proxies for the 2020-based ESRDB market basket. We note that we proposed 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 proposed to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the 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 proposed to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered ("Hospitals" and "Health Care and Social Assistance"), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.4 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 proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). As we stated in the CY 2023 ESRD PPS proposed rule, 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 proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). As we stated in the CY 2023 ESRD PPS proposed rule, 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 proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). As we stated in the CY 2023 ESRD PPS proposed rule, 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. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI blend

is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

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

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

Health Related Benefits

We proposed to continue using the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU1016220000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Management Benefits

We proposed to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2010000110000I) and the relative importance of wages and salaries within total compensation. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Administrative Benefits

We proposed to continue using the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this constructed ECI series is technically appropriate for the reason stated in the wages and salaries price proxy section.

Services Benefits

We proposed to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. As we stated in the CY 2023 ESRD PPS proposed rule, we believe this ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section. We also stated 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: ECI Blend for Benefits in the 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	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 proposed to continue using the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category.

Natural Gas

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

Pharmaceuticals

ESAs: We proposed to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI-BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. The PPI–BPHU measures the price change of prescription biologics, and ESAs will 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 explained that we do not know if these drugs are indeed reflected in this price index. However, as we stated in the CY 2023 ESRD PPS proposed rule, 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 stated that we will continue to monitor the trends in the prices for ESA drugs as

measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

Other Drugs (except ESA): For all other drugs included in the ESRD PPS bundled payment other than ESAs, we proposed 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). As we stated in the CY 2023 ESRD PPS proposed rule, 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 indicated 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 believed a different price proxy would be more appropriate and we proposed 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 noted that 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 will be captured will 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, as we stated in the CY 2023 ESRD PPS proposed rule, 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 stated that 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 50/50 PPI blend warrants an adjustment, and if so, we will propose such an adjustment in future rulemaking.

Supplies

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

Laboratory Services

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

Telephone Service

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

Housekeeping

We proposed 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 proposed to use the ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair (BLS series code #CIU1010000430000I) to measure the price growth of this cost category. This price proxy accounts for the compensation expenses related to maintenance and repair workers. As we stated in the CY 2023 ESRD PPS proposed rule, 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 proposed to continue using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this cost category.

All Other Goods and Services

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

Capital-Related Building and Fixtures

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

Capital-Related Moveable Equipment

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

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

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

Cost Category	Price Proxy	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%

Cost Category	Price Proxy	2020 Cost Weight
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.

We received several comments regarding the proposed price proxies in the 2020-based ESRDB market basket. The comments and our responses are set forth below.

Comment: Several commenters, including a coalition of dialysis organizations, supported the proposal to adopt the PPI Commodity for Pharmaceuticals for human use, prescription (BLS series code #WPUSI07003) within the blended price proxy for Non-ESA drugs in the ESRDB market basket. They stated that they believe the majority of the non-ESA drugs in the ESRD PPS bundled payment align with this proxy and not the PPI Commodity data for Chemicals and allied products-Vitamin, nutrient, and hematinic preparations. The commenters requested for CMS to monitor the impact of this change and adjust the weight of the blended proxy in future years, if appropriate, and for CMS to potentially consider breaking out the weight for the non-ESA blend formally into two separate market basket categories in the future.

Response: We appreciate the commenters' support for the proposed 50/50 blended price proxy for the Non-ESA drug cost category. We will continue to monitor the mix of the expenses for the non-ESA drugs accounted for in this category and consider if it may be appropriate to propose to adjust the cost weights of this blended price proxy through future notice and comment rulemaking.

Comment: One LDO expressed that they believe the process and indices used by CMS to capture year over year growth in the ESRDB market basket have worked relatively well since the ESRD PPS was implemented in 2011. The commenter stated that they do not object to CMS's use of the ECI for Wages and Salaries for All Civilian Workers in Hospitals as the price proxy for the ESRDB market basket's health-related occupations; however, they have concerns that the ECI is not designed to accurately capture rapid changes in inflation and market dynamics of the type seen as a result of the COVID-19 PHE. Specifically, the commenter stated that ESRD

facilities have experienced dramatic increases in overtime pay, dramatic increases in hiring bonuses, increases in travel costs, and a higher dependency on travel nurses and staffing agencies, which demand hourly rates that far exceed the average. One LDO and a non-profit dialysis association cited a study by Altarum that showed that between July 2021 and June 2022, healthcare wages grew by an average of 6.9 percent, compared to 5.1 percent for all private sector jobs. The same study showed that average hourly earnings in healthcare grew 7.4 percent, compared to 5.2 percent across all private sector jobs. The study also showed that the quantity of healthcare workers has decreased relative to the levels from before the COVID-19 PHE, reporting 78,000 fewer workers in July 2022 compared to February 2020. The nonprofit dialysis association noted that while other industries outside of healthcare may be able to fund the rising costs of labor by increasing their prices or improving efficiency, ESRD facilities are unable to do so because the majority of ESRD patients are Medicare beneficiaries, and therefore the majority of ESRD facilities' revenue is determined by the federal government. The nonprofit dialysis association further noted that ESRD facilities have specialized requirements – many of which are codified in federal regulations – for dialysis nurses, home dialysis nurse specialists, and dialysis patient care technicians, that require additional education, training, experience, and certification beyond what is often required of clinical staff in other healthcare settings. As a result, the commenter stated, ESRD facilities can be easily outbid for clinical workers by better financed hospitals, health plans, clinical practices, and other healthcare settings that may also have fewer clinical requirements.

Response: The ESRDB market basket reflects changes over time in the price of providing renal dialysis services and will not reflect increases in costs associated with changes in the volume or intensity of input goods and services. To measure price growth for ESRD facility wages and salaries costs, the ESRDB market basket relies on a blend of ECIs reflecting the occupational skill mix of FTEs as reported on the 2020 Medicare cost report forms. The majority of the weight for compensation costs is for health-related occupations, and accounts for

approximately 80 percent of the ESRD facility compensation costs. The health-related workers' Wages and Salaries, and Benefits, cost categories use the ECI for wages and salaries and the ECI for benefits for civilian hospital workers, respectively. We believe that these ECIs are the best available price proxies to account for the health-related workers' occupational skill mix within ESRDs. The BLS Occupational Employment and Wage Statistics (OEWS) data are one of the primary data sources used to derive the weights for the ECI. In 2020, which we proposed as the base year of the ESRDB market basket, a little over 56 percent of total employment for NAICS 622100 was attributed to Health Professional and Technical occupations, and approximately 13 percent was attributed to Health Service occupations. Therefore, in the absence of ESRD-specific data, we believe that the highly skilled hospital workforce captured by the ECI for hospital workers (inclusive of therapists, nurses, and other clinicians) is a reasonable proxy for the compensation component of the ESRDB market basket. Additionally, we believe that by utilizing the relative distribution of workers based on the FTE data reported on the ESRD cost report, the occupational distribution of the compensation costs weights is technically appropriate.

Comment: One LDO encouraged CMS to provide more transparency regarding the ESRDB market basket price proxies forecasting models' methodologies and underlying assumptions, and stated that greater transparency could better inform stakeholder feedback and help identify opportunities to improve the models' capacity to capture economic anomalies that facilities have encountered in recent years.

Response: We appreciate the commenter's feedback on improving the forecasting model capacity of the price proxies used in the ESRDB market basket. CMS uses independent forecasts of the price proxies for the CMS market baskets from IHS Global Inc. (IGI), a nationally recognized economic and financial forecasting firm. The rationale for using an independent forecaster is to ensure neutrality in the annual ESRDB market basket increase and productivity adjustment while reflecting comprehensive economic and health sector forecasting model capabilities that extend beyond CMS' expertise. As the forecasting models are proprietary in

nature, we are not licensed to share information related to the detailed models. More information on the IGI economic forecasts can be found at the following website, https://ihsmarkit.com/products/US-economic-modeling-forecasting-services.html.

Final Rule Action: After consideration of the public comments we received, we are finalizing the 2020-based ESRDB market basket price proxies as proposed.

(d) Rebasing Results

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38479), a comparison of the yearly differences of increase factors from CY 2019 to CY 2023 for the 2016-based ESRDB market basket and the 2020-based ESRDB market basket showed that 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 2020-based market basket was 0.1 percentage point lower. We did not receive any comments related to the comparison of the ESRDB market basket updates comparing the 2016-based and 2020-based ESRDB market baskets.

(2) Labor-Related Share for the 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 proposed to use the 2020-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Specifically, effective for CY 2023, we proposed 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 8. 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 8: Labor-Related Share of Current and ESRD Bundled Market Baskets

Cost Category	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

As discussed in the CY 2023 ESRD PPS proposed rule, 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 included 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).

As discussed in the CY 2023 ESRD PPS proposed rule, 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 noted that 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).

We received several comments regarding our calculation of the proposed labor-related share based on the 2020-based ESRDB market basket. The comments and our responses are set forth below.

Comment: Several commenters, including a coalition of dialysis organizations, a nonprofit dialysis association, and a provider advocacy organization, supported the proposed increase of the labor share from 52.3 percent to 55.2 percent, and stated that their experience is that the costs of labor are rising exponentially. The commenters further stated that they do not believe that shifting the market basket percentage alone will address the labor shortage's impact on payments and costs.

Response: We appreciate the commenters' support of the proposed labor-related share. This increase in the ESRD PPS labor-related share reflects the relative increase in labor-related costs compared to non-labor-related costs that ESRD facilities have experienced since 2016 and through 2020. We will continue to monitor the ESRD cost report data for significant changes to the ESRD cost share weights.

Final Rule Action: After consideration of the public comments we received, we are finalizing the 2020-based labor-related share of 55.2 percent effective for CY 2023, as proposed.

(3) 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 proposed to use the 2020-based ESRDB market basket as described in section II.B.1 of this final 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 proposed to estimate the ESRDB market basket increase factor based on IGI's 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) CY 2023 Market Basket Increase Factor

Based on IGI's first quarter 2022 forecast, the proposed 2020-based ESRDB market basket increase factor for CY 2023 was projected to be 2.8 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 market basket update in this final rule. Based on the more recent data available for this CY 2023 ESRD PPS final rule (that is, IGI's third quarter 2022 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2022), we estimate that the ESRD PPS CY 2023 market basket update is 3.1 percent.

(b) 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. As we noted in the CY 2023 ESRD PPS proposed rule, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously 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.[2] 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 referred 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 will 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.

As discussed in the CY 2023 ESRD PPS proposed rule, based on IGI's first quarter 2022 forecast with historical data through the fourth quarter of 2021, the proposed productivity adjustment for CY 2023 (the 10-year moving average of TFP for the period ending CY 2023) was projected to be 0.4 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this

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

final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 market basket update and productivity adjustment in this final rule. Based on the more recent data available from IGI's third quarter 2022 forecast, the current estimate of the productivity adjustment for CY 2023 is 0.1 percentage point.

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

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2023 market basket update, which is used to determine the applicable percentage increase for the ESRD PPS payments, on IGI's first quarter 2022 forecast of the 2020-based ESRDB market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for CY 2023 of 0.4 percentage point (the 10-year moving average growth of TFP for the period ending CY 2023 based on IGI's first quarter 2022 forecast). Therefore, the proposed CY 2023 ESRDB update was equal to 2.4 percent (2.8 percent market basket update reduced by the 0.4 percentage point productivity adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 market basket update and productivity adjustment in this final rule.

We invited public comment on our proposals for the CY 2023 market basket update and productivity adjustment. The following is a summary of the public comments received on the proposed CY 2023 market basket update and productivity adjustment and our responses:

Comment: Many commenters, including an LDO, a provider advocacy organization, a nonprofit dialysis association, a coalition of dialysis organizations, a network of dialysis organizations, and a professional organization, generally supported the utilization of the most recent data available (for example, a more recent estimate of the market basket and/or productivity adjustment) to determine the final CY 2023 ESRD PPS update. MedPAC

recommended that the ESRD PPS base rate increase for CY 2023 should be updated by the amount determined under current law, and that analysis reported in the March 2022 Report to the Congress: Medicare Payment Policy[3] concluded that this increase is warranted based on analysis of payment adequacy (which includes an assessment of beneficiary access, supply and capacity of facilities, facilities' access to capital, quality, and financial indicators for the sector). At the same time, other commenters expressed their concern that the CY 2023 ESRD PPS update insufficiently captures the rising costs that ESRD facilities have experienced and continue to experience, particularly the impact of the health-related compensation costs. However, commenters expressed different views about the scope and nature of the staffing challenges facing ESRD facilities. A provider advocacy organization claimed that the ongoing COVID-19 PHE is creating significant and lasting effects on staffing and supply costs. In contrast, a patient-led dialysis organization maintained that the current labor shortages are not a temporary phenomenon related to the ongoing COVID-19 PHE, but the result of a demographic shift in labor market conditions in the healthcare industry. This commenter stated that the American workforce as a whole has shrunk, and mentioned a 2008 report from the Institute of Medicine that further described the demographic shift the commenter identified.[4] Many commenters requested that CMS consider using its statutory authority to apply a labor add-on payment adjustment to the ESRD PPS for CY 2023.

Many commenters, including LDOs, ESRD facilities, professional associations, patients, provider advocacy organizations, and a coalition of dialysis organizations, stated that a labor add-on payment adjustment factor is needed because ESRD facilities have had to contend with rising costs in labor, medical supplies, and rent. They noted that the largest contributor to higher input costs is accelerating labor costs, which have been exacerbated by the nation-wide shortages

[3] https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/
[4] https://pubmed.ncbi.nlm.nih.gov/25009893/

in qualified clinical staff, and that they need to increasingly rely on contract labor, which has led to a significant, permanent increase in labor costs.

Response: We are required to update ESRD PPS bundled payments by the market basket update adjusted for productivity under section 1881(b)(14)(F)(i) of the Act, which states that the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. We believe the 2020-based ESRDB market basket increase adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, and is technically appropriate to use as the ESRD PPS payment update factor. The ESRDB market basket is a fixed-weight, Laspeyres-type index that reflects changes over time in the price of providing renal dialysis services and will not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the ESRDB market basket update will reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices), but inherently will not reflect other factors that might increase the level of costs, such as the quantity of labor used. However, as we note in section II.B.1.a.(2) of this CY 2023 ESRD PPS final rule, the 2020-based ESRDB market basket reflects an increase to the cost category weights for labor-related costs. Therefore, the final CY 2023 ESRDB market basket update reflects the most recent available data regarding both prices and the quantity of labor used to provide renal dialysis services.

We agree with the commenters who stated that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. At the time of the CY 2023 ESRD PPS proposed rule, based on the IGI first quarter 2022 forecast with historical data through the fourth quarter of 2021, the 2020-based ESRDB market basket update was forecasted to be 2.8 percent for CY 2023, reflecting forecasted compensation prices of about 3.9 percent (by comparison, compensation growth in the ESRDB market basket averaged 2.2 percent from 2012

through 2021). In the CY 2023 ESRD PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2023 ESRDB market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. Based on the IGI third quarter 2022 forecast with historical data through the second quarter of 2022, we are projecting a CY 2023 ESRDB market basket update of 3.1 percent (reflecting forecasted compensation growth of 4.5 percent) and productivity adjustment of 0.1 percentage point. Therefore, for CY 2023, a final productivity adjusted ESRDB market basket update of 3.0 percent (3.1 percent less 0.1 percentage point) will be applicable, compared to the 2.4 percent productivity adjusted ESRDB market basket update that was proposed.

As for commenters' suggestions for alternatives to the productivity-adjusted ESRDB market basket update for CY 2023, as noted previously, we are required by statute to update ESRD PPS payments by the market basket update adjusted for productivity. Any change to the productivity adjusted-market basket update would require legislation to amend the statute. While we acknowledge the commenters' suggestions that we apply an add-on payment adjustment to the ESRD PPS for CY 2023 to account for increasing labor costs, we note that we did not propose to establish an add-on payment adjustment for labor under section 1881(b)(14)(D)(iv) of the Act or to use other methods or data sources to update ESRD PPS payment rates for CY 2023, and we are not finalizing such an approach for this final rule. We proposed to update ESRD PPS payments by the market basket update, which is consistent with the statute and our longstanding policy for updating the ESRD PPS base rate. We do not believe it would be appropriate to apply additional adjustments to the ESRD PPS base rate to circumvent the statutorily-required market basket update. Further, as discussed earlier in this section of this final rule, we are finalizing our proposal to rebase the ESRDB market basket to reflect more

recent data on ESRD facility cost structures, and we believe this rebased ESRDB market basket appropriately reflects the prospective price pressures described by the commenters as increasing during a high inflation period. Consistent with our proposal, we have used more recent data to calculate a final ESRDB productivity-adjusted market basket update of 3.0 percent for CY 2023.

Comment: Several commenters, including an LDO and a coalition of dialysis organizations, recognized that CMS does not have the authority to eliminate the productivity adjustment from the annual ESRD PPS update calculation, but stated that they continue to be concerned by the historically small and even negative Medicare margins, and that the experience of ESRD facilities is contrary to the idea that productivity can be improved year-over-year. The commenters also stated their view that the current productivity adjustment does not capture factors unique to ESRD facilities, such as required staffing structures or operational changes required due to the impact of the COVID-19 PHE, including establishing cohort clinics to minimize disruptions in care that can impede improvements in productivity.

One LDO stated that CMS's current approach, which applies the same adjustment across the board to other sectors subject to a reduction for productivity, is a blunt instrument. This commenter recommended that CMS work with the kidney care community and policymakers to revisit this policy and devise a productivity adjustment that: (1) better reflects factors over which ESRD facilities have control and that affect opportunity for productivity gains, and (2) accounts for the statutory reductions to the ESRD PPS already in place to account for expected gains in efficiency.

Response: We acknowledge the commenters' concerns regarding productivity growth at the economy-wide level and its application to ESRD facilities; however, as the commenters acknowledge, section 1881(b)(14)(F)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket increase factor for 2012 and subsequent years. As required by statute, the CY 2023 productivity adjustment is derived based on the 10-year moving average growth in economy-wide

productivity for the period ending CY 2023. We will continue to monitor the impact of the ESRD PPS updates, including the effects of the productivity adjustment, on ESRD facility margins as well as beneficiary access to care as reported by MedPAC in their annual Report to the Congress.

Comment: Many commenters, including LDOs, ESRD facilities, professional associations, patients, provider advocacy organizations, and a coalition of dialysis organizations, requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during this inflationary period, particularly accounting for what commenters state is an error in the forecasted payment updates for CYs 2021 and 2022. The commenters stated that forecasted payment updates that they view as incorrect, coupled with the impact of the workforce shortage, have put them in financial difficulty. The commenters suggested that CMS should apply the actual percent increase in the market basket for the two CYs, 2021 and 2022, where the forecast missed its mark. The commenters highlighted that CMS has applied this type of an adjustment in other parts of the Medicare program historically, such as for SNFs, and could do so for the ESRD PPS on a temporary or even permanent basis. A couple of commenters recommended that the forecast error correction could be designed and implemented in a manner similar to the SNF market basket forecast error correction, triggered by positive and negative forecast errors that exceed 0.5 percentage points.

One provider advocacy organization stated that they understand that this is not a customary practice for CMS, but these extraordinary times call for extraordinary measures and CMS has discretion to implement a forecast error adjustment based on section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. This commenter further stated that while they recognize that updates to the ESRD market basket are set prospectively, and some degree of forecast error is inevitable, ESRD facilities should not be financially disadvantaged as a result of CMS market basket forecasting errors. This commenter, along with one LDO, stated that they

believe establishing a forecast error payment adjustment in the ESRD PPS is within CMS' existing statutory authority under section 1881(b)(F)(i)(I) of the Act.

Several commenters, including an LDO, a coalition of dialysis organizations, and a nonprofit dialysis association, stated that failure to correct for the missed IGI forecast error projections of the market basket updates for CYs 2021 and 2022 will result in chronic underfunding of the ESRD PPS going forward. These commenters stated that each successive update to the ESRD PPS base rate will be building on a previous rate that has never accounted for the large and rapid inflationary trends in CY 2021 through CY 2023. One LDO and a coalition of dialysis organizations further expressed that a forecast error payment adjustment is imperative given the Medicare ESRD PPS's current narrow margins and the fact that over 90 percent of the ESRD beneficiaries rely on Medicare coverage.

Response: As discussed previously, the ESRDB market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated, and forecasted data for the remainder. For instance, the CY 2023 market basket update in this final rule reflects historical data through the second quarter of CY 2022 and forecasted data through the fourth quarter of CY 2023. While there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase.[5] Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was -0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage point; CY 2022 historical data is not yet available to calculate a forecast error for CY 2022.

5 FAQ - Market Basket Definitions and General Information. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf

As discussed earlier in this section of this final rule, our longstanding policy since the inception of the ESRD PPS has been to update ESRD PPS payments based on an appropriate market basket in accordance with section 1881(b)(14)(F)(i) of the Act. For this final rule, we have incorporated more recent historical data and forecasts, which utilize the most current projections of expected future price and wage pressures likely to be faced by ESRD facilities to provide renal dialysis services. We did not propose a forecast error payment adjustment for CY 2023, and we are not finalizing such an adjustment for this final rule. As we have discussed in past rulemaking (85 FR 71434; 80 FR 69031) and in section II.B.1.b.(2) of this final rule, predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations. As we noted earlier in this section, forecast error calculations are unpredictable, and can be both positive and negative. We note that over longer periods of time, the positive differences between the actual and forecasted market basket increase in prior years can offset negative differences; therefore, we do not believe it is necessary to implement a forecast error payment adjustment for the ESRD PPS based solely on a positive CY 2021 forecast error.

Final Rule Action: After consideration of the comments we received, we are finalizing a CY 2023 ESRDB productivity-adjusted market basket increase of 3.0 percent based on the most recent data available. As noted previously, based on the more recent data available for this CY 2023 ESRD PPS final rule (that is, IGI's third quarter 2022 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2022), the CY 2023 ESRDB market basket update is 3.1 percent. Based on the more recent data available from IGI's third quarter 2022 forecast, the current estimate of the productivity adjustment for CY 2023 is 0.1 percentage point. Therefore, the current estimate of the CY 2023 ESRD productivity-adjusted market basket increase factor is equal to 3.0 percent (3.1 percent market basket update reduced by 0.1 percentage point productivity adjustment).

b. 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 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 proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We proposed to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d) (10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 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 applied 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 applied 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 final rule, the labor-related share to which the wage index will be applied is 55.2 percent, based on the 2020-based ESRDB market basket.

For CY 2023, we proposed to update the ESRD PPS wage index to use the most recent hospital wage data. The 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 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.

We received several comments on our proposal to update the ESRD PPS wage index. The comments and our responses are set forth below.

Comment: Four commenters, including an ESRD facility, a physician, and a dialysis administrator, expressed concerns that the ESRD PPS wage index does not reflect the realities faced by dialysis clinics and would lead to too low payments to hire and retain staff. These commenters pointed to inflation and the COVID-19 PHE as main factors driving the increase in healthcare wages. Several commenters representing a network of rural ESRD facilities indicated that they thought the wage index was too low for their area, not accurately reflecting the cost of labor.

Response: We appreciate the concerns that commenters raised; however, we did not propose to change the wage index methodology for CY 2023 and are not finalizing any changes to that methodology in this final rule. The wage data used to construct the ESRD PPS wage index are updated annually, based on the most current data available, and are based on OMB's CBSA delineations when applying the rural definitions and corresponding wage index values. As discussed in CY 2011 ESRD PPS final rule (75 FR 49200), the wage index reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Because the wage index is scaled relative to the national average, it does not reflect changes over time to the cost of labor. Rather, it is the market basket increase which accounts for national trends, including inflation. As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38480), we proposed to increase the ESRD PPS base rate for CY 2023 by the market basket increase factor in accordance with section 1881(b)(14)(F)(i) of the Act, which provides that the market basket increase factor should reflect the changes over time in the prices

of an appropriate mix of goods and services that reflect the costs of furnishing renal dialysis services. As discussed in section II.B.1.a.(3) of this CY 2023 ESRD PPS final rule, the final productivity-adjusted market basket update for CY 2023 is 3.0 percent based on the latest available data. We note that this final update is 0.6 percentage point higher than the proposed update and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2023 for ESRD facilities. We believe the final productivity adjusted market basket update will address some of the commenters' concerns regarding rising wages due to inflation.

Comment: Several commenters suggested changes to the wage index methodology. One professional association and one non-profit dialysis facility suggested CMS use a wage index methodology for the ESRD PPS that is consistent with the inpatient payment wage index policies, including using a different labor-related share for ESRD facilities with a low wage index. A non-profit health insurance organization in Puerto Rico suggested CMS implement a payment adjustment for clinics with wage index values in the lowest quartile, similar to the system used by IPPS. A non-profit health insurance organization in Puerto Rico and a healthcare group in Puerto Rico expressed a desire for CMS to create a new wage index based only on data from ESRD facilities. These commenters claimed that the current wage index based on hospital data is inadequate given the differences in staffing needs between ESRD facilities and hospitals.

Response: We appreciate the commenters' suggestions for modifying the methodology for the ESRD PPS wage index. We did not propose changes to the ESRD PPS wage index methodology for CY 2023, and therefore we are not finalizing any changes to that methodology in this final rule. As discussed in section II.B.1.b.(2) of this final rule, we are finalizing a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, and as discussed in section II.B.1.b.(3) of this final rule, we are finalizing an increase to the wage index floor from 0.5000 to 0.6000. We believe that these final policies will address some of the underlying concerns of the commenters by assisting in the higher labor costs affecting low wage index areas, maintaining the ESRD PPS wage index as a relative measure of

the value of labor in prescribed labor market areas, increasing predictability of ESRD PPS payments for ESRD facilities, and mitigating instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. We did not propose and are not finalizing other methodological changes that commenters suggested; however, we will take these comments into consideration to potentially inform future rulemaking.

Final Rule Action: We are finalizing our proposal to update the ESRD PPS wage index for CY 2023 to use the most recent hospital wage data, as proposed.

(2) Permanent Cap on Wage Index Decreases

As discussed in section II.B.1.b.(1) of this final 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[6] 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

[6] 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.

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 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.

In the CY 2023 ESRD PPS proposed rule (87 FR 38482), we noted that based on our past wage index transition policies and public comments, we recognized 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, in the CY 2023 ESRD PPS proposed rule, we considered how best to address those scenarios.

We explained that 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 to ensure the accuracy of the ESRD PPS wage index, in accordance with § 413.196(d)(2). As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38482) as well as earlier in this section of the final 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 recognized 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, we noted in the proposed rule that 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 recognized that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations.

In light of these considerations, we proposed 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 proposed a policy that we believed 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.

In the CY 2023 ESRD PPS proposed rule, we stated that we believed 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 stated that we believed this methodology mitigated short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. We also stated that we believed 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, we recognized 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. Therefore, we proposed a permanent policy that we believed 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).

As we noted in the CY 2023 ESRD PPS proposed rule (87 FR 38482), typical year-to-year variation in the ESRD PPS wage index has historically been within 5 percent, and we expected this would continue to be the case in future years. We explained that, because ESRD facilities are usually experienced with this level of wage index fluctuation, we believed 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 stated, we believed this approach would address concerns about instability that commenters raised in response to the CY 2021 ESRD PPS proposed rule. In addition, we stated that we believed 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 stated that we believed it would still ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. We noted that 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) 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. We discussed that we would compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. We estimated 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. We stated that 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[7] 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 anticipated 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 anticipated that the impact to the wage index budget neutrality factor in future years would continue to be minimal. We also stated that we believed that when the 5-percent cap would be applied under this 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 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 stated that we believed 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, 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. We stated in the CY 2023 ESRD PPS proposed rule that we believed a 5-percent cap on wage index decreases would be appropriate for the ESRD PPS. Therefore, for CY 2023 and subsequent

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

years, we proposed 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, 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 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. We noted 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 stated 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 proposed to reflect the permanent cap on wage index decreases in our regulations at § 413.231(c).

We received several comments on our proposal to establish a permanent cap on wage index decreases for the ESRD PPS. The comments and our responses are set forth below.

Comment: Commenters broadly supported the proposed 5-percent cap on wage index decreases. A coalition of dialysis organizations expressed appreciation that CMS recognized the need for greater predictability to avoid negative impacts on ESRD facilities, but noted that the wage index continues to raise concern among many of its members and that a conversation around the wage index and the implications of the budget neutrality requirement should take place. One LDO encouraged CMS to also engage with the kidney care community and use its statutory authority to develop and apply an alternative to the hospital wage index.

Response: We thank the commenters for their support. We also appreciate the general concerns that commenters raised about the wage index. We did not propose for CY 2023 any of

the changes to the ESRD PPS wage index that these commenters suggested, but we will take these suggestions into consideration to potentially inform future rulemaking.

Comment: MedPAC supported the proposal to cap wage index decreases at 5 percent, but suggested also applying a cap to wage index increases of more than 5 percent.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38482), one purpose of the proposed policy is to help mitigate the significant negative impacts of certain wage index changes. As we noted in the proposed rule, 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. That is, we proposed to cap decreases because we believe that an ESRD facility would be able to more effectively budget and plan when there is predictability about its expected minimum level of ESRD PPS payments in the upcoming CY. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable ESRD facilities to more effectively budget and plan their operations. For these reasons, we believe it is appropriate for ESRD facilities that experience an increase in their wage index value to receive that wage index value.

Comment: Several commenters, including a nonprofit dialysis association, an LDO, and a couple of independent ESRD facilities encouraged CMS to implement the proposed 5-percent cap in a way that would protect facilities that experienced substantial reductions to their wage index due to the adoption of the new CBSA delineations in CY 2021.

Response: As we noted earlier in this final rule, 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. We indicated that no cap would be applied to the reduction in the second year, CY 2022. 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. We have historically implemented transitions of limited duration, such as in the CY 2015 ESRD PPS final rule (79 FR 66142), to address CBSA changes due to substantial updates to OMB delineations. As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38482) and earlier in this final rule, our policy is generally to use the most current hospital wage data and analysis available to ensure the accuracy of the ESRD PPS wage index, in accordance with § 413.196(d)(2). In accordance with this general policy, we proposed to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS and the most recent prior-year ESRD PPS wage index to determine the facilities to which the 5-percent cap would apply in CY 2023. We proposed that the CY 2023 ESRD PPS 5-percent cap wage index policy would be prospective to mitigate any significant decreases beginning in CY 2023.

Final Rule Action: After consideration of the comments received, for CY 2023 and subsequent years, we are finalizing as proposed a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, which we will apply in a budget-neutral manner. This means that an ESRD facility's wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, and for subsequent years, an ESRD facility's wage index will not be less than 95 percent of its wage index calculated in the prior CY. Also, 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 will not be less than 95 percent of the ESRD facility's capped wage index in the prior CY. We are also finalizing as proposed that a newly opened or newly certified ESRD facility will 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 will reflect the permanent cap on wage index decreases in our regulations at § 413.231(c) by stating that 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.

As previously discussed in this final rule, we believe this mitigation policy will 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 final rule, we estimate the impact to payments for ESRD facilities in CY 2023 based on this policy. We also note that we will examine the effects of this policy on an ongoing basis in the future to assess its continued appropriateness.

(3) 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 and feedback 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, to 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[8] (ranging between

[8] 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-

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 final 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

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explained/index.php?title=Glossary:Laspeyres_price_index#:~:text=The%20Laspeyres%20price%20index%20is,cost%20in%20the%20current%20period)

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 final 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) CY 2023 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, in the CY 2023 ESRD PPS proposed rule (87 FR 38483 through 38486), we proposed to increase the wage index floor 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 proposed to increase the wage index floor to 0.6000. We stated that we believed that this wage floor increase is responsive to comments from interested parties, safeguards access to care in areas at the lowest end of the current wage index distribution, and is 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

We explained that 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 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 final rule and discussed in the CY 2019 ESRD PPS final rule (83 FR 56967), commenters have noted that both 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 the CY 2023 ESRD PPS proposed rule, we stated that in response to comments and our continued concern regarding access, we were revisiting the CY 2019 analysis, and believed 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 Final Rule Analytic File

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38385 through 38486), we performed an analysis to compare the impact of three options to adjust the wage index floor upward using the CY 2023 ESRD PPS final rule analytic file. The analytic file included 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 proposed base rate for CY 2023 (87 FR 38485). 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 proposed base rate of $264.11 and $264.09, respectively. We noted that these options would decrease the ESRD PPS base rate due to the application of the budget neutrality factor for each option, however as discussed in the following paragraph, we noted that the overall impact to ESRD PPS payments would be negligible.

Next, we examined the potential impact to the proposed outlier thresholds for CY 2023. Relative to the baseline (wage index floor value of 0.5000), all options would have little or no impact on either the proposed 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 proposed budget neutrality factor for each option, we noted in the proposed rule that 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 estimated that the change in overall payments attributable to increasing the wage index floor would be less than 0.01 percentage point. However, we estimated 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 estimated 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 estimated 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, 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, we stated, 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 proposed 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 noted that 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 final rule, we identified that 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 the CY 2023 ESRD PPS proposed rule, we proposed to increase the wage index floor to 0.6000. We stated that we believed our analyses supported that wage index floor value and would strike the right balance between providing increased payment 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 proposed to amend § 413.231 by adding new paragraph (d) to reflect this change and to codify the wage index floor policy. We stated we believed this 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 0.6002. All CBSAs in Puerto Rico would be subject to the wage index floor of 0.6000. Though the wage index floor value currently would only affect areas in Puerto Rico, we noted that, consistent with our established policy, the proposed wage index floor value of 6.000 would be applicable for any area that may fall below the floor.

We solicited comment on the proposal to increase the wage index floor from 0.5000 to 0.6000. The comments and our responses are set forth below.

Comment: MedPAC expressed opposition to the proposed wage index floor increase and expressed that wage index floors and related policies distort area wage indexes. MedPAC recommended that CMS establish an ESRD PPS wage index for all ESRD facilities using wage

data that represents all employers and industry-specific occupational weights, rather than the hospital wage data currently used. Several commenters also agreed with MedPAC's recommendation to establish a wage index specific to ESRD facilities.

Response: We appreciate MedPAC's comments, but we do not agree with the suggestion that the proposed wage index floor would distort area wage indexes under the ESRD PPS. As our analysis shows, wage indexes below the lower fence of 0.5936 are statistical outliers, so the application of the floor would serve to improve rather than distort the accuracy of the ESRD PPS wage index overall. Further, our analysis of the impact to the ESRD PPS base rate indicates that the proposed wage index floor would strike the right balance between providing increased payment 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.

We appreciate the feedback that we should use wage data that represents all employers and industry-specific occupational weights for the ESRD PPS wage index. We note that for our analysis to determine if the wage index floor could be appropriately set at a higher value, we used wage data from the BLS and FTEs by occupation reported on the cost reports for independent ESRD facilities. Specifically, we calculated labor weights by occupation for Puerto Rico and the greater U.S. as the treatment weighted average of the FTEs reported on independent facility cost reports. We did not include hospital-based cost report data because the occupations for which the FTEs were reported were not identical between independent and hospital-based cost reports. Although an ESRD facility wage index that more specifically targets the labor mix applicable to ESRD facilities could potentially identify more granular cost differences between labor market areas, some commenters expressed concern that it could increase the reporting burden on ESRD facilities. We appreciate MedPAC's suggestions for establishing a new wage index for the ESRD PPS and may consider these recommendations for potential future rulemaking.

Comment: Several commenters, including a national dialysis provider, an LDO, and an insurance organization, expressed support for finalizing the wage index floor policy as proposed. The commenters who supported our proposal stated that a wage index floor increase to 0.6000 would improve access and quality of care for Medicare ESRD beneficiaries in Puerto Rico, given that all areas with wage index values below the floor are in Puerto Rico. These commenters stated that a wage index floor of 0.6000 would improve equality amongst all ESRD facilities given that the next lowest wage index value outside of Puerto Rico is the Virgin Islands, with a proposed wage index value of 0.6004. These commenters stated that health equity in the Medicare program would be served by minimizing payment disparities between the lowest and highest paid ESRD facilities.

Response: We thank the commenters for their support of the wage index floor proposal. We are aiming to strike a balance between providing increased payment to areas where actual labor costs are higher than the current wage index indicates while minimizing the overall impact to all ESRD facilities. We believe a wage index floor of 0.6000 is appropriate and will support labor costs in low wage areas.

Comment: While most commenters supported finalizing the wage index floor policy as proposed, these same commenters also stated that CMS should consider future refinements to the wage index floor policy. Commenters claimed that the current analysis is based on the data from cost reports from the years 2013 through 2015. Commenters explained that since 2015, the economic situation in Puerto Rico has worsened due to natural disasters, PHEs, post COVID-19 inflation, and new economic measures imposed under the Puerto Rico Oversight, Management, and Economic Stability Act. The commenters stated that CMS should conduct new analysis of cost reports for free-standing and hospital-based ESRD facilities in Puerto Rico and increase the wage index floor to 0.7000.

Response: As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38483 through 38486), we revisited our analysis using ESRD facility cost reports and wage information specific

to Puerto Rico from the BLS utilizing data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015. We used this data to determine if the wage index floor could be appropriately set at a higher value. We did not propose to use these analyses to determine the exact value for a new wage index floor. Instead, we considered the cost report analyses, along with the analysis of the CY 2023 ESRD PPS proposed rule analytic file, to determine a higher wage index floor, which assists ESRD facilities in areas with low wage index levels while maintaining the accuracy of payments under the ESRD PPS. We appreciate these recommendations regarding our wage index floor analysis and may consider these suggestions for potential future rulemaking.

In our efforts to strike a balance between resource use and payment, we also stated in the CY 2023 ESRD PPS proposed rule (87 FR 38484 through 38486) that our analysis of several options using the most recent analytic file for the CY 2023 proposed rule showed that a higher wage index floor will slightly decrease the ESRD PPS base rate for all ESRD facilities due to the application of the budget neutrality factor. Given that increasing the wage index floor results in proportional decrease in the base rate for all facilities, we must establish a value that that maintains the accuracy of payments under the ESRD PPS. An increase to the wage index floor to 0.6000 is a 20 percent increase over the current wage index floor and will provide a higher wage index for all facilities in areas that fall below the floor, which are currently all located in Puerto Rico, and will assist in the higher labor costs affecting low wage index areas. We continue to believe that a wage index floor of 0.6000 strikes an appropriate balance between providing additional payments to areas that fall below the wage index floor while minimizing the impact on average payment rates for all ESRD facilities.

Comment: Some commenters made additional comments regarding Puerto Rico and the staffing difficulties ESRD facilities face there. Commenters expressed their belief that failing economic factors have led to a relocation of health care professionals from Puerto Rico to the U.S. mainland. Commenters expressed their belief that ESRD facilities have had to increase

wages to retain qualified staff. Commenters stated that under local regulation, Puerto Rico ESRD facilities can only employ Registered Nurses (RNs) rather than technicians for medical care. Commenters also stated that under local regulation, RNs and other ESRD facility staff in Puerto Rico must be bilingual. Commenters explained that for these reasons ESRD facility staff are costlier in Puerto Rico.

Response: We thank commenters for the additional information regarding ESRD facilities in Puerto Rico. We have codified the wage index policy and our methodology at § 413.231. As discussed previously, we adjust the labor-related portion of the base rate to account for geographic difference is area wage 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. To acquire such data to develop the wage index annually, changes in labor costs are captured in the survey of wages and wage-related costs derived from the MCRs, the Hospital Wage Index Occupational Mix Survey, hospitals' payroll records, contracts, and other wage-related documentation. This process is utilized by other Medicare prospective payment systems. We appreciate the additional information regarding the staffing costs in Puerto Rico; however, we believe that Puerto Rico's labor costs should be captured in the wage-related documentation used for the development of the annual wage index.

Regarding concerns raised about the need to hire bilingual RNs, the need for bilingual staff occurs in both inpatient and outpatient settings and hospital cost reports should reflect those additional costs. As stated in the CY 2019 ESRD PPS final rule (83 FR 56967), we note that in every analysis we conducted, the average salary of RNs in Puerto Rico was approximately half that of mainland facilities and none of the analyses produced a 0.7000 wage index value.

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

index floor under the ESRD PPS in that context in future rulemaking. We note that any changes to the ESRD PPS wage index floor would be proposed through notice and comment rulemaking.

Comment: Commenters expressed their belief that health disparities in the patient population in Puerto Rico justify a higher wage index floor than proposed. Commenters stated that diabetes is rampant in Puerto Rico and that its prevalence is higher in the Puerto Rican population compared to the U.S. The commenters further stated that diabetes is a primary cause of kidney failure, heart disease, and cardiac chronic related conditions. Commenters stated that Puerto Rico has prominent levels of disease burden resulting in higher complex care needs and higher costs.

Response: The wage index payment adjustment is intended to recognize geographic differences in wage levels in areas in which ESRD facilities are located. We do not believe it would be appropriate to raise the wage index floor to mitigate other issues such as non-labor costs or costs associated with issues of disease burden disparities.

Final Rule Action: After considering the public comments we received regarding the wage index floor, we are finalizing an increase to the wage index floor from 0.5000 to 0.6000 for CY 2023 and subsequent years as proposed. In addition, we are amending § 413.231 by adding new paragraph (d) to reflect this change and to codify the wage index floor policy. Section 413.231(d) will provide that 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.

c. 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.[9]

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.[10] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly

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[9] 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.

[10] 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

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 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 final rule 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 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 final 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 2 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)[11]. 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[12]. 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 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 final rule. The imputed MAP amounts for each of these services

[11] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf
[12] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_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 (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[13]. 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 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 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

[13] 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.

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 9 and 10 in this section. A more detailed description of the steps is provided in the following paragraphs.

TABLE 9: 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

TABLE 10: 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

Patient Characteristics		Outlier Services Multipliers		
<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

As discussed in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49140), 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.

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 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 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. Following the methodology adopted in the CY 2016 ESRD PPS final rule (80 FR 68989), we calculate the exponent of the PM for BSA by subtracting the national average BSA from John's BSA and dividing by 0.1. Applying the ESRD outlier services multiplier set forth in Table 9 of this final 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 9, 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

As we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38493), 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.

We explained in the CY 2023 ESRD PPS proposed rule (87 FR 38490 through 38491) that, 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 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[14], we received comments from major national patient and provider organizations and MedPAC on the RFI regarding the outlier policy.

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

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 maintained 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 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.

(4) Changes to the Outlier Methodology for CY 2023

In response to significant public comments received over many years, in the CY 2023 ESRD PPS proposed rule (87 FR 38491 through 38493), we proposed changes to the outlier policy for CY 2023 and subsequent years. As we discussed in the proposed rule, we considered the three main suggestions that commenters raised in response to the CY 2022 RFI in developing these proposed changes.

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 stated that we were 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 stated that we were 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 stated that we were 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 did not propose 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 final 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[15], 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, will 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. In the CY 2023 ESRD PPS proposed rule, we stated that we agreed with the concerns this organization raised, and believed that these challenges would make it difficult to accurately operationalize commenters'

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

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 did not propose to establish a payment reconciliation methodology for the ESRD PPS outlier policy.

Lastly, we discussed in the CY 2023 ESRD PPS proposed rule that 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[16] in the CY 2022 ESRD PPS proposed rule expressed that using a retrospective FDL trend based on historical utilization data will provide a better calculation of the appropriate prospective FDL amounts. These organizations also cautioned that such a methodology will remain sensitive to changes in utilization or price increases for new and innovative products. Commenters suggested that such a methodology will 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

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

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.

We also noted that in the CY 2022 ESRD PPS final rule (86 FR 36402), we 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[17] to eliminate network adequacy standards that apply to ESRD facilities. 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 may occur, commenters claimed 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, in the CY 2023 ESRD PPS proposed rule, we proposed 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 stated that we believed that our proposed methodology would also adapt to changes in the ESRD PPS patient population, such as the potential scenario

[17] 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).

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 final 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 final 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 proposed to continue to calculate the adult and pediatric MAP amounts for the rule year (CY 2023) following our established methodology, but we would 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 also proposed 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 noted in the proposed rule that we did not propose to apply this method to pediatric FDL amount calculations, as the pediatric population is too small to reliably use this method.

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38492 through 38493), we proposed 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. 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. 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. 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.

We received several comments on our proposal to modify the outlier methodology. Those comments and our responses are set forth below.

Comment: Several commenters urged CMS to reduce the outlier percentage from 1.0 percent to 0.5 or 0.6 percent. A provider advocacy organization further claimed that even if CMS were to achieve the full 1 percent outlier target, $82 million in ESRD PPS expenditures would be withheld from ESRD facilities until a later date when outlier payment adjustments were processed and distributed. This commenter recommended that CMS reduce the percentage of payments allocated for the outlier pool from 1 percent to 0.5 percent to ensure the maximum amount of up-front funds flow to ESRD facilities during this time of crisis currently being driven by staffing shortages and inflationary pressures. A small and rural dialysis provider voiced similar concerns and claimed that reducing the outlier percentage to 0.5 percent would serve ESRD patients by helping to keep their units open.

Response: As discussed in the CY 2023 ESRD PPS proposed rule, 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. If we were to reduce the outlier percentage, we would then need to increase the FDL amount which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Regarding the comment about money being withheld from ESRD facilities, we note that outlier payments are paid as an adjustment to the ESRD PPS base rate, so payment is made when the ESRD claim is paid. There is no reason that outlier payments would be processed or paid at a later date than any other payments under the ESRD PPS.

We appreciate the concerns commenters raised about staffing shortages and inflationary pressures, and we agree with the commenters who stated that recent higher inflationary trends have impacted the outlook for price growth over the next several quarters. As discussed in

section II.B.1.a.(3)(c) of this final rule, we are finalizing a 3.0 percent increase to the productivity-adjusted ESRDB market basket for CY 2023. We believe that this final update to the market basket more accurately accounts for the recent inflationary pressures and changes in the cost of labor that commenters cited.

Comment: Several commenters expressed their belief that the outlier policy results in money being withheld from ESRD facilities and not returned to them, due to the fact that the ESRD PPS achieved less than the 1 percent outlier target in past years. A provider advocacy organization claimed that from 2019 to 2021, the outlier policy has resulted in over $150 million in Medicare dollars designated for the ESRD PPS outlier pool but not ultimately released to ESRD facilities. An LDO estimated that total "leakage" from the outlier pool exceeds $500 million as of CY 2021 and encouraged CMS to consider that a payment reconciliation methodology or other additional measures may be necessary to stem what they described as the loss of patient care dollars from the ESRD PPS. Some commenters suggested reducing a subsequent year's target percent or applying a mechanism to restore unspent outlier dollars to the ESRD PPS.

Response: While we appreciate the concerns that commenters raised, we note that ESRD PPS payment policy is set prospectively. That is, we establish the outlier FDL and MAP amounts each year at a level that our analysis indicates will effectively protect access for the costliest beneficiaries while maintaining an appropriate ESRD PPS base rate for all other beneficiaries. As discussed previously, we did not propose, nor are we finalizing, to establish a payment reconciliation methodology for the ESRD PPS outlier policy for CY 2023, because we considered that lags in the claims process and refiling of claims, often over different calendar years, would present challenges to such an approach.

Regarding the suggestion to reduce a subsequent year's target outlier percentage, we do not believe this approach would be appropriate at this time. As noted earlier in this final rule and discussed in the CY 2023 ESRD PPS proposed rule, 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. If we were to reduce the outlier percentage, we would then need to increase the FDL amount which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Rather, we believe the proposed methodology is the most appropriate, because it better aligns assumptions about future trends in prices and utilization of ESRD outlier services with actual trends in the utilization of such services.

Comment: A provider advocacy organization expressed concern about the impact of the outlier policy on pediatric ESRD facilities, and stated that instead of attempting to qualify more cases for outlier payments, CMS should analyze the cost of providing care in pediatric facilities and develop a pediatric-specific ESRD PPS base rate to appropriately compensate these specialized facilities for their work. A professional organization of pediatric nephrologists expressed similar concerns, and recommended that CMS adopt a pediatric modifier to appropriately reimburse for pediatric care, since the proposed continuation of the longstanding outlier policy applies to such a small number of pediatric patients that it does not adequately address costs.

Response: We appreciate the concerns these commenters raised about payment adequacy for pediatric patients. In the CY 2022 ESRD PPS proposed rule (86 FR 36402 through 36404), we solicited comments on ESRD PPS payment for pediatric patients. In the CY 2022 ESRD PPS final rule (86 FR 61997), we noted similar concerns from commenters that the total costs of ESRD care delivered to pediatric dialysis patients are not covered by the current ESRD PPS bundled payment and existing pediatric multipliers. Additionally, as discussed in section II.E of this final rule, we received comments in response to our RFI in the CY 2023 ESRD PPS proposed rule about ways to address payment disparities for pediatric patients. We appreciate the thoughtful responses that commenters provided to both of these comment solicitations, and will take them into consideration to potentially inform future rulemaking.

While we agree with commenters that the ESRD PPS outlier policy alone is not sufficient to account for the costs of furnishing renal dialysis services to pediatric beneficiaries, we continue to believe that an outlier policy is important for paying an adequate amount for the most costly, resource-intensive pediatric patients. As we noted in the CY 2011 ESRD PPS final rule (75 FR 49139), our longstanding methodology establishes separate FDL and MAP amounts for pediatric and adult beneficiaries so that the outlier thresholds for determining outlier payments for pediatric patients are not inappropriately high, resulting in fewer outlier payments for these beneficiaries.

Comment: Several commenters, including a network of dialysis organizations and regional offices, a nonprofit dialysis association, a coalition of dialysis organizations, MedPAC, and an LDO, expressed support for the proposed change to the outlier methodology. A network of dialysis organizations and regional offices further stated they support the outlier payment adjustment as an appropriate protection for patients who utilize significantly more services than the average patient.

MedPAC supported the proposed methodology and acknowledged that it is likely to improve outlier payment accuracy, but also urged CMS to refine its approach for applying the pricing data that the agency uses to project FDL amounts, particularly for drugs. MedPAC suggested CMS use a drug price inflation factor based on ASP values, and noted that the ASP data that CMS uses to determine facilities' actual outlier payments might be a more accurate data source on drug prices than the ESRDB market basket pharmaceutical price proxies that are currently used.

Lastly, one LDO encouraged CMS to monitor the performance of the outlier payment adjustment under the proposed methodology. A coalition of dialysis organizations expressed support for the proposed change to the outlier methodology and encouraged CMS to continue sharing any under- or over-payment from the outlier pool and consider ways to adjust the target outlier percentage as needed.

Response: We appreciate commenters' support for the proposed change to the outlier methodology. We intend to continue to monitor the performance of the outlier policy on an ongoing basis and continue to publish information in our annual rules in the **Federal Register** about the performance of the outlier policy in the future. We appreciate the methodological suggestions that commenters provided. Although we are not finalizing those changes in this final rule, we will take these suggestions into consideration to potentially inform future rulemaking.

Comment: A nonprofit dialysis association and an LDO expressed concerns about using TDAPA and TPNIES expenditures in the calculation of the FDL and MAP amounts. The LDO claimed that the inclusion of these expenditures has the potential to increase the dollars withheld from the ESRD PPS base rate and result in the outlier pool paying less than the 1 percent target. The nonprofit dialysis association claimed that the proposed methodology would not succeed in estimating the outlier pool in years where there were significant changes to the ESRD PPS, such as in years when CMS incorporates new ESRD outlier services that were previously paid for using the TDAPA or the TPNIES into the ESRD PPS bundled payment.

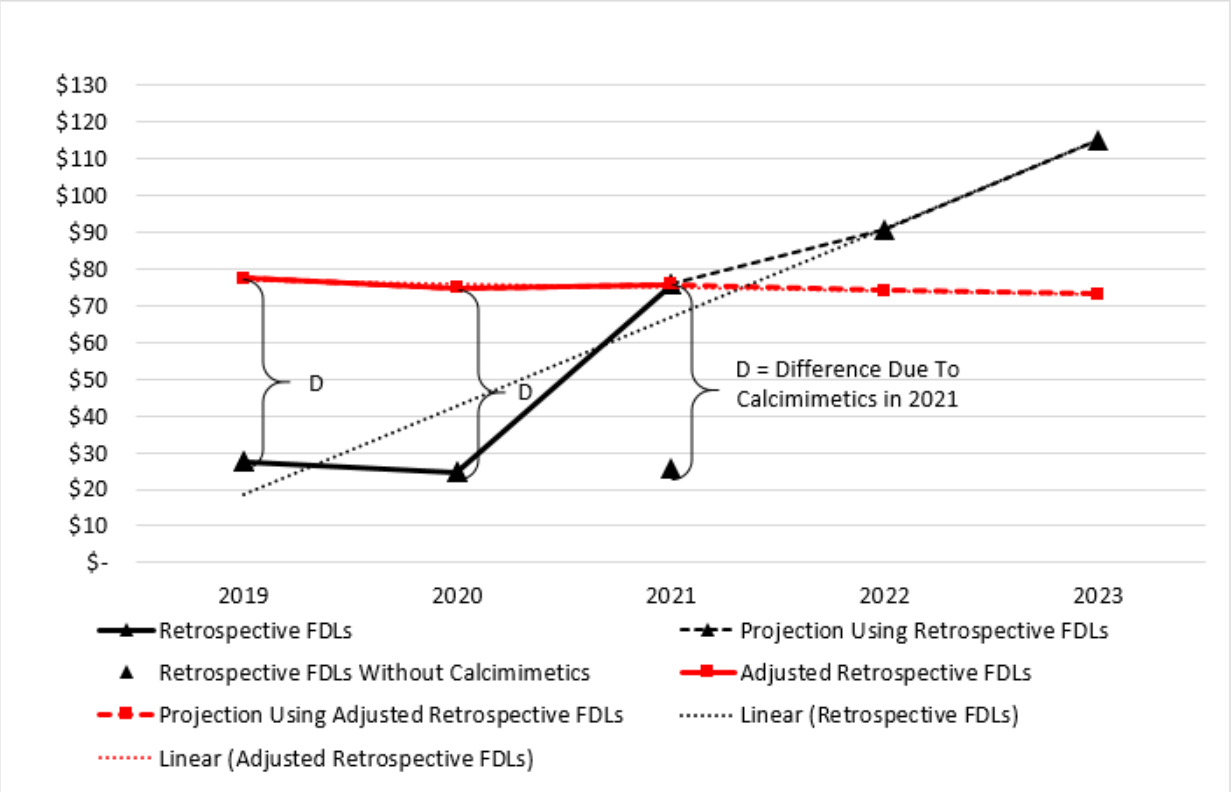
Response: We believe that these commenters have misunderstood how TDAPA and TPNIES expenditures would be used in the proposed outlier methodology, as well as the effect that including these expenditures would have on outlier payments. As the commenters correctly noted, any renal dialysis service that is paid for using the TDAPA or the TPNIES would not be considered an eligible ESRD outlier service. However, following the conclusion of the TDAPA or TPNIES payment period, certain renal dialysis services would become eligible ESRD outlier services. Under our proposed methodology, which we are finalizing, we will only include expenditures for renal dialysis services that are in their final year of payment under the TDAPA or the TPNIES if those services would become eligible ESRD outlier services in the following (target) year. We did not propose to include any TDAPA or TPNIES expenditures in our estimates of ESRD outlier payments for setting the FDL and MAP amounts for any services that

would not be eligible ESRD outlier services in the target year. We also proposed to account for the introduction of such new eligible ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization. Because these expenditures will be added to the retrospective FDLs to calculate the adjusted retrospective FDLs under the proposed methodology, our inclusion of TDAPA or TPNIES utilization will always reduce the slope of the trend line of the adjusted retrospective FDL, as demonstrated in Figure 1. Therefore, contrary to the concerns that commenters raised, this inclusion of TDAPA and TPNIES utilization data will avoid overestimating ESRD outlier expenditures in years when new renal dialysis services are added to the ESRD PPS bundled payment and will reduce the likelihood of paying less than the 1 percent outlier target.

Final Rule Action: After careful consideration of the comments, we are finalizing our proposed methodology for prospectively calculating the adult FDL amounts for the outlier policy beginning for CY 2023.

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 final methodology. The adjusted retrospective FDL amounts shown in Figure 1 will 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 methodology will 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.

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



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

For CY 2023, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2021 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2021 claims data, and 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 final rule.

We also stated that we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. CY 2021 claims data showed outlier payments represented approximately 0.5 percent of total payments. Accordingly, as discussed in section II.B.1.c.(4) of this final rule, we are changing our ESRD PPS outlier methodology to better target 1.0 percent of total payments.

For this final rule, the outlier services MAP amounts and pediatric FDL amounts for CY 2023 were updated based on 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 and our proposal for CY 2023. The adult FDL amounts for CY 2023 were derived from the projected FDL trend calculated according to the methodology described in section II.B.1.c.(4) of this final rule that we are finalizing for CY 2023.

The impact of this update is shown in Table 11, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2022 with the updated final estimates for this final rule. The estimates for the final CY 2023 MAP amounts, which are included in Column II of Table 11, were inflation adjusted to reflect projected 2023 prices for ESRD outlier services.

TABLE 11: Outlier Policy: Impact of Using Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)*		**Column II Final 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	$24.13	$41.36
Adjustments				
Standardization for outlier services	1.0693	0.9805	1.0819	0.9774
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$27.15	$42.75	$25.59	$39.62
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$26.02	$75.39	$23.29	$73.19
Patient-month-facilities qualifying for outlier payment	12.89%	7.08%	12.90%	5.90%

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

As demonstrated in Table 11, the estimated FDL per treatment that determines the CY 2023 outlier threshold amount for adults (Column II; $73.19) 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 $39.62. For pediatric patients, there is a decrease in the FDL amount from $26.02 to $23.29. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $27.15 to $25.59.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2023 will be 5.90 percent for adult patients and 12.90 percent for pediatric patients, based on the 2021 claims data and methodology finalized in section II.B.1.c.(4) of this final 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 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services.

As we stated in the CY 2023 ESRD PPS proposed rule (87 FR 38494), recalibration of the thresholds using 2021 data and the proposed methodology, which is further described in section II.B.1.c.(4) of this final rule, is expected to result in aggregate outlier payments closer to the 1 percent target in CY 2023. We stated in the CY 2023 ESRD PPS proposed rule that we believed finalizing the proposed 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 noted in the CY 2023 ESRD PPS proposed rule 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.

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

Comment: Several commenters noted that the outlier policy has historically achieved less than the 1 percent target, and recommended that CMS eliminate the ESRD PPS outlier policy. One small dialysis organization within a large health system stated that they appreciate CMS's willingness to address outlier payments but expressed concern that the outlier provision is not working as intended. Several commenters, including MedPAC, LDOs, and a network of dialysis organizations and regional offices, expressed support for the outlier policy and the proposed adjustment to the methodology for calculating the FDL amount for adults.

Response: We appreciate the support from commenters. Regarding the commenters who recommended the elimination of the outlier policy, we note that as we discussed earlier in this CY 2023 ESRD PPS final rule, we are concerned that reducing the outlier percentage to 0 would not provide the appropriate level of payment for outlier cases, and may not protect access for beneficiaries whose care is unusually costly.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2023 displayed in Column II of Table 11 of this final rule and based on CY 2021 data.

d. Final 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

The final ESRD PPS base rate for CY 2023 is $265.57. This update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2023, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 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 will 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 CY 2023 ESRD PPS wage index and labor-related share for CY 2023. As discussed in section II.B.1.b of this final rule, the 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 final rule, we are increasing the ESRD PPS wage index floor from

0.5000 to 0.6000 and applying 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 wage index budget-neutrality adjustment factor is 0.999730. This application would yield a CY 2023 ESRD PPS base rate of $257.83 prior to the application of the market basket increase factor ($257.90 × 0.999730 = $257.83). This CY 2023 wage index budget-neutrality adjustment factor reflects the impact of all wage index policy changes, including the CY 2023 ESRD PPS wage index and labor-related share, increase to the wage index floor, and permanent 5-percent cap on wage index decreases.

For purposes of illustration and analysis, we also calculated a separate budget neutrality factor to estimate the impact that the 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 CY 2023 ESRD PPS final rule, we divided estimated payments without the 5-percent cap by estimated payments with the cap. We calculated the resulting budget neutrality factor as 0.999905. Applying this budget neutrality factor to the ESRD PPS base rate, we estimate that the permanent 5-percent cap would result in a $0.02 decrease to the ESRD PPS base rate ($257.90 x 0.999905 = $257.88). The overall CY 2023 wage index budget-neutrality adjustment factor is lower because of the effects on budget neutrality of the updated CY 2023 wage index data.

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 ESRDB market basket percentage increase factor is 3.1 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 final rule, the productivity adjustment for CY 2023 is 0.1 percent, thus yielding an update to the base rate of 3.0 percent for CY 2023. Therefore, the CY 2023 ESRD PPS base rate is $265.57 ($257.90 × 0.999730 × 1.030 = $265.57).

The comments and our responses to the comments on our proposed updates to the ESRD PPS base rate are set forth below.

Comment: Several commenters expressed concerns with the proposed update to the ESRD PPS base rate for CY 2023. Many commenters, including LDOs, ESRD facilities, professional associations, patients, provider advocacy organizations, and a coalition of dialysis organizations, requested that CMS apply a forecast error payment adjustment to the ESRD PPS base rate to support ESRD facilities during this inflationary period, particularly accounting for what forecasters state is an error in the forecasted payment updates for CYs 2021 and 2022. The commenters stated that forecasted payment updates that they view as incorrect, coupled with the impact of the workforce shortage, have put them in financial difficulty. A coalition of dialysis organizations and a non-profit dialysis association both noted that if CMS were to adjust the CY 2022 base rate for forecast error, the CY 2022 base rate would have been $263.21, which would result in a calculated CY 2023 proposed base rate of $269.53 rather than the proposed $264.09.

Response: As we discussed in section II.B.1.a.(3)(c) of this CY 2023 ESRD PPS final rule, there is no precedent to adjust for market basket forecast error in the annual ESRD PPS update; however, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase. Due to the

uncertainty regarding future price trends, forecast errors can be both positive and negative. For example, the CY 2017 ESRDB forecast error was -0.8 percentage point, while the CY 2021 ESRDB forecast error was +1.2 percentage point; CY 2022 historical data is not yet available to calculate a forecast error for CY 2022.

We further noted in section II.B.1.a.(3)(c) of this final rule that our longstanding policy since the inception of the ESRD PPS has been to update ESRD PPS payments based on an appropriate market basket in accordance with section 1881(b)(14)(F)(i) of the Act. For this final rule, we have incorporated more recent historical data and forecasts, which utilize the most current projections of expected future price and wage pressures likely to be faced by ESRD facilities to provide renal dialysis services. We did not propose a forecast error payment adjustment for CY 2023, and we are not finalizing such an adjustment for this final rule. As we have discussed in past rulemaking (85 FR 71434; 80 FR 69031) and in section II.B.1.b.(2) of this final rule, predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations. As we noted in section II.B.1.a.(3)(c) of this final rule, forecast error calculations are unpredictable, and can be both positive and negative. We note that over longer periods of time, the positive differences between the actual and forecasted market basket increase in prior years can offset negative differences; therefore, we do not believe it is necessary to implement a forecast error adjustment for the ESRD PPS based solely on a positive CY 2021 forecast error.

Final Rule Action: After consideration of the public comments received, we are finalizing a CY 2023 ESRD PPS base rate of $265.57. This amount reflects the CY 2023 wage index budget-neutrality adjustment factor of 0.999730, and the CY 2023 ESRD PPS productivity-adjusted market basket update of 3.0 percent.

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 final 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.

We proposed a CY 2023 TPNIES offset amount for capital-related assets that are home dialysis machines of $9.73, based on the proposed CY 2023 ESRDB market basket increase factor minus the productivity adjustment of 2.4 percent (2.8 percent minus 0.4 percentage point). We explained in the CY 2023 ESRD PPS proposed rule that applying the proposed update factor of 1.024 to the CY 2022 offset amount resulted in the proposed CY 2023 offset amount of $9.73 ($9.50 × 1.024 = $9.73). We proposed to update this calculation to use the most recent data available in the CY 2023 ESRD PPS final rule.

We received 5 comments on this proposal, including comments from an LDO, small dialysis organization, a home dialysis advocacy organization, a coalition of dialysis organizations, and a provider advocacy organization. The comments and our responses to the comments on the proposed update to the TPNIES offset amount are set forth below.

Comment: All of the commenters on this proposal expressed concern about the proposed application of the TPNIES offset amount for CY 2023. Two commenters expressed that the application of the TPNIES offset amount blunts the potential positive impact of the TPNIES. The LDO agreed with the application of the TPNIES offset amount but expressed that the current policy may diminish innovation and limit resources necessary for ESRD facilities to incorporate new and innovative equipment and supplies into their practices. The home dialysis advocacy organization expressed opposition to the application of the TPNIES offset amount but expressed appreciation for the proposed use of the market basket update factor to update the TPNIES offset adjustment amount.

Response*:* We appreciate the concerns that these commenters raised. As discussed in the CY 2021 ESRD PPS final rule (85 FR 71422 through 71423), we finalized an offset amount so that the TPNIES will cover the estimated marginal costs of new and innovative home dialysis machines. ESRD facilities using the new and innovative home dialysis machine receive a per treatment payment to cover some of the cost of the new machine per treatment minus a per treatment payment amount that we estimate to be included in the ESRD PPS base rate for current home dialysis machines that they already own. Because we have received questions about how the TPNIES offset amount is included in the calculation of payments under the ESRD PPS, we are clarifying that under the policy at § 413.236(f)(iii) that was established in the CY 2020 ESRD PPS final rule, the annually-adjusted offset amount is subtracted from the MAC-determined price to account for the cost of home dialysis machine that is already in the ESRD PPS base rate. We disagree with the commenters who stated that the TPNIES offset will lead to decreased resources or less innovation. Rather, the TPNIES offset amount prevents duplicate payment under the ESRD PPS for a service which is already included in the ESRD PPS base rate.

Final Rule Action: We are finalizing our proposal to calculate the CY 2023 TPNIES offset amount using the most recent data available. The CY 2022 TPNIES offset amount for

capital-related equipment that are home dialysis machines used in the home is $9.50. As discussed previously in section II.B.1.a of this final rule, the final CY 2023 ESRDB market basket increase factor minus the productivity adjustment is 3.0 percent (3.1 percent minus 0.1 percent). Applying the update factor of 1.030 to the CY 2022 TPNIES offset amount results in a final CY 2023 TPNIES offset amount of $9.79 ($9.50 x 1.030).

f. 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[18] 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

[18] 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.

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 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 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 will 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.[19] 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,

[19] 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.

effective January 1, 2021,[20] 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.[21]

As we explained in the CY 2023 ESRD PPS proposed rule (87 FR 38498), 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 and utilization 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 the most recently available data.

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

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

[21] 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.

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38497), 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. We noted that our observations, presented below, provided 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 Quarter 1 2018, which was the beginning of the TDAPA period for calcimimetics, and Quarter 4 2020. We stated that we believed 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. To mitigate the risk of potential access issues for minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, we stated that we believed 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 final rule.

We stated in the proposed rule that 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 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.[22] 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.

We noted that 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 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

[22] 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

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 explained in the CY 2023 ESRD PPS proposed rule that 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 noted that we continue to monitor these health outcomes on an ongoing basis.

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

We noted in the CY 2023 ESRD PPS proposed rule that, 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 we noted previously in the proposed rule and this section of the final 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.[23]

We noted that 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[24], 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

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[23] 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.

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

Part D spending for dialysis beneficiaries. The most recent CMS data through December 2021 indicates that total spending on phosphate binders is approximately $ $714 million. The average spending per treatment of phosphate binders in 2021 is approximately $20.09 among all adult ESRD beneficiaries, and $25.02 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[25], 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 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 final 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 FDA. In the CY 2023 ESRD PPS proposed rule, we noted that there are various types of drug equivalences that are defined in regulation by FDA, including

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

pharmaceutical equivalents, bioequivalence, and therapeutic equivalents.[26] 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".[27] We stated that we believed that the history of the ESRD PPS and our longstanding drug designation process indicate that CMS must consider "functional" equivalence, which is not a term defined in FDA's regulations, 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. We noted that for purposes of the 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

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[26] FDA has defined the terms "pharmaceutical equivalents", "bioequivalence", and "therapeutic equivalents" at 21 CFR 314.3(b). In FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), therapeutic equivalence is used in the context of "therapeutic equivalents" as that term is defined in § 314.3(b) (i.e., drug products containing the same active ingredient(s), among other requirements) 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.

[27] 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.

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 final 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) 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, in the CY 2023

ESRD PPS proposed rule, we proposed 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 proposed a modification to 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 proposed 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 proposed this change for several reasons. First, we noted that it would be consistent with the policies previously established for phosphate binders and calcimimetics. As discussed previously, 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 stated in the proposed rule that we believed that a revision to the oral-only drug definition to clarify that a drug is not an oral-only drug if it has a 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 stated that we believed we could still take action at this time to ensure that our drug designation process clearly reflects the longstanding ESRD PPS functional category framework.

In addition, we explained in the proposed rule, this change would help ensure that we do not perpetuate any further access issues for renal dialysis services to disadvantaged ESRD beneficiaries through delayed incorporation into the ESRD PPS payment. 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. We stated that we believed 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.

We noted that the 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 clearly define 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, either immediately, or through the TDAPA eligibility, even if the

functional equivalents are not "chemical equivalents"[28] (that is, products containing identical amounts of the same active drug ingredient). We noted that 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).

As we noted in the CY 2023 ESRD PPS proposed rule, 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 final rule, the inclusion of Medicare Part D drugs into the ESRD PPS and the corresponding expansion of access to these drugs have 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 stated that we believed the 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

[28] Like functional equivalence, chemical equivalence is not a term defined in FDA's regulations. CMS is using the term chemical equivalents for the purpose of the ESRD PPS.

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.

We noted that, when compared with all FFS beneficiaries, FFS beneficiaries receiving dialysis are disproportionately young, male, and African-American, have disabilities and low income as measured by dual status, and reside in an urban setting. We stated that we believed 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 requirement would support the goals of Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities through the Federal Government (86 FR 7009), which required Federal agencies to conduct an equity assessment and determine whether new policies, regulations, or guidance documents may be necessary to advance equity in agency actions and programs. In addition, advancing health equity is the first pillar of CMS's 2022 strategic plan (https://www.cms.gov/cms-strategic-plan), and this policy is consistent with that pillar of the agency's strategic plan.

In summary, as discussed in the CY 23 ESRD PPS proposed rule (87 FR 38500), we believed that a change 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. We solicited comments on this proposal.

We received public comments on our proposal to modify the definition of oral-only drug from MedPAC, a trade association, a drug manufacturer, a non-profit kidney organization, an LDO, a non-profit kidney care alliance, a national advocacy organization, a coalition of dialysis organizations, and a non-profit dialysis organization. The comments on our proposal and our responses are set forth below.

Comment: Overall, commenters expressed support for the proposed change to the definition of oral-only drug to specify that equivalence refers to functional equivalence. MedPAC expressed that this proposal would help maintain the integrity of the ESRD PPS bundled payment. An LDO stated that it agreed that clarifying that "equivalence" refers to "functional equivalence" better aligns with the current drug designation process. A non-profit dialysis organization commented that they think it is reasonable for CMS to refine the definition to specify that an oral-only drug or biological product need not be "chemically identical" to its intravenous counterpart. A non-profit kidney care alliance stated that it agreed with the proposed change to the definition, noting that it is reasonable to expect that a new drug or biological product would add value and not merely be a copycat product. Commenters generally supported CMS' effort to clarify the definition of an oral-only drug. However, a drug manufacturer expressed concern that CMS would apply the concept of functional equivalence across the entire ESRD PPS functional category and noted their concern that drugs for very different conditions could be treated as functional equivalents in a way that is not clinically appropriate and may, in fact, cause harm to the patient. A coalition of dialysis organizations recommended that CMS clearly state that the end action effect definition apply more narrowly within the ESRD PPS functional categories to the classes of products within the relevant functional category. Similarly, a drug manufacturer and non-profit kidney organization recommended that within the determination of functional equivalence, that is, end action effect, CMS should consider drug

comparison at the drug class or subgroup level and not the functional category level. One commenter suggested this recommendation regarding drug class or subgroup would accomplish CMS' goal of refining the definition of drugs and biological products that qualify as oral only drugs while not setting an inappropriate precedent of comparing a single drug or biological product to an entire ESRD PPS functional category. A non-profit dialysis association noted that they do not believe that Congress, when it drew a distinction in statute related to oral-only drugs, intended to allow CMS to compare one product to an entire functional category of products.

Some commenters expressed concern that the functional equivalent categorization process sends a negative signal to manufacturers and stifles innovation. One commenter stated manufacturers have reported that there has been a significant decline in demand for certain types of drugs since the ESRD PPS bundled payment went into effect. One commenter recommended that CMS eliminate the ESRD PPS functional categories as a basis for payment policy through the drug designation process. Some commenters asked CMS to define functional categories by the "FDA-[approved] indication(s)," which they believe is a more objective way to ensure consistency in the categories.

Response: We appreciate the support from certain commenters regarding the proposed change to the definition of an oral-only drug to specify that equivalence means functional equivalence. We disagree with the commenters who suggested that functional equivalence for an oral-only drug be evaluated on mechanism of action and not end action effect, as that would be inconsistent with our longstanding policy. In the CY 2016 ESRD PPS final rule, we clarified that the ESRD PPS functional categories are not based on their mechanism of action, but rather their end action effect (80 FR 69015 through 69017). Accordingly, and as noted previously in this section of this final 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). We do not base the functional category

determination by comparing the new drug or biological products to other drugs or biological products in the functional category. CMS reviews a new FDA-approved drug or biological product based on CMS' assessment of the end action effect and the description of the functional category. This review considers, but is not solely based on, the FDA-approved indication(s). The functional categories do not have classes and subclasses within the categories, and we do not think creating such a delineation or relying on mechanism of action is necessary or appropriate. CMS has been using the broader concept of end action effect in the context of ESRD PPS since the program's inception in 2011, so CMS is following longstanding precedent in this circumstance.

Regarding the suggestion that CMS should classify drugs by their FDA-approved indications rather than their end use function, CMS notes that functional substitutes for renal dialysis drugs and biological products were discussed when the ESRD PPS bundled payment was first constructed as a way to identify drugs that were appropriate to include in the ESRD PPS base rate. We used functional classification in ESRD payment prior to the establishment of the ESRD PPS in CY 2011. Specifically, regarding drugs that are included in the composite rate, in the CY 2011 ESRD PPS final rule, we specifically stated that drugs that are used as a substitute for any of these (composite rate) items, or are used to accomplish the same effect, are also covered in the composite rate (75 FR 49048). We also noted in the CY 2011 ESRD PPS final rule (75 FR 49048) that the composite rate includes the following: heparin, heparin antidotes, lidocaine, and local anesthetics, which are access management drugs; saline and mannitol, which are used for fluid management; Benadryl, an anti-pruritic drug; and antibiotics, which are anti-infectives. In the CY 2011 ESRD PPS final rule (75 FR 49049) one commenter noted that ESRD-related drugs used in the treatment of anemia and bone disease should be (75 FR 49058) included in the ESRD PPS bundled payment. CMS agreed and established the renal dialysis service ESRD drug categories included in the final ESRD PPS base rate, which included anemia management and bone and mineral metabolism (75 FR 49050). Categorizing

drugs in this way permitted CMS to determine what categories of drugs are routinely used for the treatment of ESRD and should be included in the bundled payment. These categories simplified and expedited the process of adding new drugs to the bundled payment as they became available.

Regarding the concern that drugs for very different conditions could be treated as functional equivalents in a way that is not clinically appropriate and may, in fact, cause harm to the patient, we disagree. We believe that the functional category framework helps ensure that the ESRD PPS appropriately supports the unique needs of each ESRD patient. In the CY 2019 ESRD PPS final rule (83 FR 56928) 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). This allows the practitioner to tailor the pharmaceutical plan of care of the individual patient, considering their unique clinical and personal profile. In addition, as we noted in the CY 2023 ESRD PPS proposed rule (87 FR 38500), the functional category framework supports 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 facilitate adding new drugs.

Finally, CMS supports innovation through many mechanisms under the ESRD PPS, including the use of the TDAPA for certain new renal dialysis drugs and biological products. Regarding the suggestion that CMS eliminate the functional categories as the basis for payment, we believe this would undermine the ESRD PPS bundled payment. The use of functional categories and functional equivalence, in the context of the ESRD PPS, supported the goals of the MIPPA, including the incorporation of the composite rate services into the ESRD PPS bundled payment (75 FR 49036), which already included drugs and their substitutes used to accomplish the same effect (75 FR 49048).

Comment: Two commenters requested more information on the process CMS would use to determine functional equivalence, factors CMS would consider in making functional equivalence decisions, the transparency that would be provided for interested parties as these

decisions are made, and the mechanisms for engaging with CMS as part of this process. A trade association requested that we provide specific details on which office in CMS would make the functional equivalence decision, who runs the office, and their qualifications.

Response: We appreciate and understand the requests for more transparency. The standard for determining functional equivalence is in the definitions of an oral-only drug and ESRD functional PPS category as set forth in § 413.234(a). In the CY 2023 ESRD PPS proposed rule, CMS outlined the history of the oral-only drugs and biological products and the history of the ESRD PPS functional categories, going back to the CY 2011 ESRD PPS rulemaking (87 FR 38499 through 38503). The determination of whether a new drug or biological product is included in an ESRD PPS functional category is an element of the drug designation process. More information about the drug designation process can be found in the Medicare Benefit Policy Manual, Pub. 100-2, Chapter 11, Section 20.3.1.[29] As noted in the CY 2016 ESRD PPS final rule (80 FR 69018 through 69019), to determine whether a product is a new injectable or intravenous drug or biological product, whether the new injectable or intravenous drug or biological product is a renal dialysis service, and whether the new injectable or intravenous drug or biological product fits into an existing functional category, CMS will review the data and information in the new product's FDA approved physician labeling, review the new product's information presented for obtaining a HCPCS code, and conduct an internal medical review following the announcement of the new product's FDA approval and HCPCS decision.

CMS experts, including medical officers, our contractor, along with their clinicians, work collaboratively on the structure of the ESRD PPS functional categories, including renal dialysis service drugs and biological products that may be suitable and appropriate for inclusion in the ESRD PPS bundled payment. The drug designation process is connected to the TDAPA application process, which is described at https://www.cms.gov/Medicare/Medicare-Fee-for-

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

Service-Payment/ESRDpayment/ESRD-Transitional-Drug. Specifically, we determine whether the new drug is a renal dialysis service, whether it is within an existing functional category, and whether the drug is eligible for TDAPA. For certain drugs, the TDAPA eligibility process involves CMS looking at New Drug Application classifications made by the FDA (84 FR 60657 through 60668). TDAPA eligibility determinations are released to the public via the CMS Change Request process.

Comment: A trade association, an LDO, a coalition of dialysis organizations, and a pharmaceutical company recommended CMS adopt an objective clinical standard to serve as the basis for functional equivalence when comparing drugs or biological products by relying upon FDA-approved indications for those drugs and biological products, which they believe is a more objective way to ensure consistency in the categories. They recommended that CMS rely on the expertise and role of FDA to make functional equivalence determinations.

Response: FDA is responsible for approving drugs and biological products based on safety and efficacy. CMS's functional category determination relies, in part, on FDA's expertise, as CMS considers FDA's marketing approval of a drug or biological product and the information contained in the drug or biological product's FDA-approved labeling as part of the basis for the functional category determination. In addition, § 413.234(a) states that a new renal dialysis drug or biological product is an injectable, intravenous, oral, or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by FDA on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025. There are also additional factors considered in the determination for TDAPA eligibility. It is CMS's role, not the role of FDA, to make determinations about the ESRD PPS payment policy. We believe that the history of the

ESRD PPS and our longstanding drug designation process indicate it is proper for us to consider "functional" equivalence 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. This history and CMS' reliance on functional equivalence when assessing drugs and biological products as oral-only drugs and the placement of drugs and biological products in ESRD PPS functional categories is described in length in this section of this final rule.

Comment: We also received several comments related to issues that we either did not discuss in the CY 2023 ESRD PPS proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes. Some commenters suggested oral-only drugs, specifically phosphate binders, should be separately payable indefinitely and should be permanently excluded from the ESRD PPS bundled payment. Some commenters were concerned that adding drugs to the ESRD PPS bundled payment may reduce utilization and patients would lose access to oral-only drugs that would impact their care. Some drug manufacturers suggested that oral-only drugs should continue to be accessed and paid for under Medicare Part D. One commenter focused their comments on CMS paying for oral-only drugs that are dispensed versus those that are consumed in the billing period. The commenter also asked CMS to address what it views as the lack of access to renal dialysis service drugs in the Medicare Advantage program.

Response: With regard to carving out some oral-only drugs, such as phosphate binders, from the ESRD PPS bundled payment and paying separately for them, we emphasize it was always CMS's intention to pay for oral-only drugs as part of the ESRD PPS bundled payment (75 FR 49038 through 49039). Regarding access to renal dialysis service drugs by Medicare beneficiaries, our data has shown that more Medicare patients, especially minorities, who are receiving dialysis have better access to drugs and biological products when those drugs and biological products are part of the ESRD PPS bundled payment. Regarding the comment about access to renal dialysis services in the Medicare Advantage program, we expect that Medicare

ESRD beneficiaries would have access to the same renal dialysis services covered under Parts A and B when they are enrolled in the Medicare Advantage program.[30]

We have previously addressed the request for a change in billing guidance for ESRD facilities to report amount dispensed versus the amount consumed in the CY 2018 ESRD PPS final rule (82 FR 50753). Although we are not specifically addressing comments that are out-of-scope of the CY 2023 ESRD PPS proposed rule or topics for which we did not propose changes, we thank the commenters for their input and may consider the recommendations in future rulemaking.

Final Rule Action: After consideration of the comments received and for the reasons outlined in the proposed rule and earlier in this section of the final rule, we are finalizing our proposal to include the word "functional" in the definition of oral-only drug at § 413.234(a). To apply this change effective January 1, 2025 as proposed, we are finalizing a technical modification to the amendatory language to update the regulation text at § 413.234(a). Accordingly, we are updating the definition of oral-only drug at § 413.234(a) (effective January 1, 2025) to read as follows: "*Oral-only drug.* A drug or biological product with no injectable functional equivalent or other form of administration other than an oral form."

(6) 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 to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal

[30] Except for the instances specified in 42 CFR 422.318 (for entitlement that begins or ends during a hospital stay) and 42 CFR 422.320 (with respect to hospice care), an Medicare Advantage organization offering an MA plan must provide enrollees in that plan with all Part A and Part B original Medicare services [see Section 1852(a)(1)(A) of the Act and 42 CFR 422.100(c)(1)], including covered services under Original Medicare related to treatment of ESRD if the enrollee is entitled to benefits under both parts, and Part B services if the enrollee is a grandfathered "Part B only" enrollee. The Medicare Advantage Organization fulfills its obligation of providing original Medicare benefits by furnishing the benefits directly, through arrangements, or by paying for the benefits on behalf of enrollees. As noted in 42 CFR 422.112(a), an MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. Therefore, Medicare Advantage enrollees with ESRD may need to receive dialysis services from in-network providers to avoid full financial liability of the cost of the service.

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 will 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 will 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.[31] 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)).

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

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 the CY 2023 ESRD PPS proposed rule (87 FR 38502-38503), we explained that carefully reviewed the descriptions for the existing ESRD PPS functional categories and proposed certain clarifications to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. We noted that these modifications 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), we noted 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 proposed 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 proposed 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.

As published in the CY 2023 ESRD PPS proposed rule (87 FR 38503), the clarifications to the descriptions of the ESRD PPS functional categories are shown in italics in Table 12 of this final rule.

TABLE 12: 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.

We solicited comments on this proposal and received public comments from four organizations: MedPAC, a physicians' professional association, a drug manufacturer, and a coalition of dialysis organizations. The comments and our responses are set forth below.

Comment: MedPAC supported the proposed revisions to the descriptions of the ESRD PPS functional categories. The Commission noted that an important goal of the ESRD PPS is to

give ESRD facilities an incentive to provide ESRD-related items and services as efficiently as possible. They stated that this goal is best achieved by relying on the ESRD bundled payment to the greatest extent possible when determining payment amounts. Additionally, they expressed that including all items and services with a similar function in the ESRD PPS bundled payment fosters competition for ESRD-related items and services and generates incentives for dialysis providers to constrain their costs.

Response: We agree with MedPAC's assessment and thank them for their support of our proposal.

Comment: Two of the commenters suggested CMS should not proceed with its proposed clarifications to the ESRD PPS functional category descriptions, as more details are necessary to explain the full intent of these changes. One of these commenters suggested the proposed clarifications were "substantive changes" to the ESRD PPS functional category, thus needing more clarification on CMS's intent.

Response: Just as CMS did in the CY 2016 ESRD PPS final rule (80 FR 69017), we are taking the opportunity in this rule to make clarifying modifications to our descriptions of some of the ESRD PPS functional categories to more precisely describe the drugs and biological products that will fit into the categories. In the CY 2023 ESRD PPS proposed rule, we explained that these proposed changes would help ensure our descriptions are as clear as possible for potential TDAPA applicants and the public (87 FR 38502). Additionally, we explained that 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. In addition, we have stated that the intent of the ESRD PPS functional category framework is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician (83 FR 56941). We believe these clarifications are consistent with these goals and will help ensure that potential TDAPA

applicants and the public have a clear picture of the drugs and biological products that will fit into each category.

Comment: One commenter noted multiple examples of functional categories including products for multiple indications. They suggested there is no clinical basis to group drugs or biological products that are for the treatment of different clinical indications into broader categories, such as the "functional categories." They stated that in assigning these drugs and biological products to the same functional category, CMS has created a "nexus" between these drugs that does not exist to the clinician or the patient.

Response: With regard to the functional categories including products with multiple indications, it has not been our intent to exclude a drug from a functional category because it has multiple indications. Rather, the functional category structure helps to ensure the ESRD patient has broad access to all renal dialysis service drugs, which is a distinct benefit to the patient. In addition, the structure of the functional categories helps to ensure the treating physician has a broad array of drugs to meet the specific, individual needs of each ESRD patient, including differing pharmaceutical profiles, co-morbidities, contra-indications with other drugs the patient may be taking, and personal patient preference. To the extent the functional categories create a nexus between the drugs and biological products in the categories, this nexus is for payment purposes under the ESRD PPS and we believe it is beneficial for patients and their clinicians.

CMS initially placed drugs and biological products in the functional categories to group the drugs and biological products by end action when used for the treatment of ESRD and thus ensure they are included in the ESRD PPS base rate and not separately payable (79 FR 66149 through 66150). The functional categories have been critical to the drug designation process and the inclusion of new drugs and biological products into the base rate. As stated previously in this section of this rule, in the CY 2016 ESRD PPS final rule (80 FR 69017), we defined 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 discuss at length the use of "end action effect" in determining functional categories. Although clinical indications are part of the information CMS uses in making a functional category decision for new drugs and biological products, it is not the sole basis.

Comment: Physician members of the coalition of dialysis organizations commented on our proposed addition of the phrase "secondary to dialysis" to the antipruritic and bone mineral metabolism ESRD PPS functional category descriptions. They stated that these products are not secondary to dialysis, which is a procedure and not a patient condition. These commenters claimed that these products are secondary to kidney disease, and they suggested that CMS adopt more clinically appropriate language. Another commenter stated they do not understand CMS's intent in using the phrase "secondary to dialysis" in the antipruritic and anxiolytic functional categories. This commenter noted that their clinicians do not recognize "secondary to dialysis" as a clinical term. They further questioned CMS' intent in changing the language from "related to dialysis" to "secondary to dialysis." The coalition of dialysis organizations stated that it assumes that CMS intends for these phrases to have different meanings, but cannot discern what that difference may be. They requested clarification on the intent of the change and stated they will not support any changes intended to expand the scope of the functional categories.

Response: As we explained in the CY 2023 ESRD PPS proposed rule (87 FR 38502), 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. Our intent in proposing the clarifications to these functional category descriptions was not to expand the scope of the functional categories, but rather to more clearly describe them. CMS has previously used the phrase "secondary to dialysis" in some of the descriptions of past rules. For example, the phrase "secondary to dialysis" was used in Table 8A presenting the ESRD PPS functional categories in the CY 2016 ESRD PPS proposed rule (80 FR 37832) and final rule (80 FR 69015 through 69016). In both rules, the phrase was used

in the rationale for association for the same three categories that we proposed to use it in now, that is, antiemetic, antipruritic, and anxiolytic. In the CY 2019 ESRD PPS proposed rule (83 FR 34310) and final rule (83 FR 56928), we replaced the phrase "secondary to dialysis" with "related to dialysis" in those three functional categories. That modification did not provide the clarity we had anticipated, and some interested parties incorrectly interpreted this language as changing the scope of these functional categories. Therefore, we proposed to revert back to our original language, "secondary to dialysis," in the description of these three categories in the context of other proposed modifications to the functional category descriptions. The provision of renal dialysis services is central to the ESRD PPS, and all renal dialysis service drugs and biological products are "secondary to dialysis." Therefore, we believe the phrase "secondary to dialysis" is a term that appropriately reflects that the drugs and biological products in these categories are included for the treatment of ESRD-related conditions in a dialysis unit, either during or between dialysis treatments. Finally, as we did not propose to clarify the description of the bone and mineral metabolism category in the CY 2023 ESRD PPS proposed rule, the phrase "secondary to dialysis" in that functional category description remains unchanged.

Comment: Regarding the bone and mineral metabolism functional category, one commenter expressed confusion as to whether the proposed addition of "Examples of drugs/biological products" is intended merely to clarify that phosphate binders and calcimimetics are included in the bone and mineral metabolism functional category or if CMS intends this new language to be a mechanism to expand the scope of the bone and mineral metabolism functional category. The commenter stated that it does not support language that expands the scope of the bone and mineral metabolism functional category.

Response: We stated in the proposed rule that 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 (87 FR 38502). These clarifications are meant to address some questions raised

by applicants that indicated to us that our wording could leave room for interpretation on issues where we felt our policy intent was clear. In particular, we wanted to clarify that biological products are also included in the categories, examples are not exhaustive lists, and drugs and biological products with single indications are not excluded from any functional categories that include drugs and biological products with multiple indications.

Comment: For the antipruritic functional category, one commenter noted that given the recent approval of KORSUVA™, it is important for CMS to affirm that we are not proposing any retroactive changes to the antipruritic functional category.

Response: CMS affirmed the disposition of antipruritic drug KORSUVA™ (difelikefalin) in both the CY 2023 ESRD PPS proposed rule (87 FR 38502) and again in this section of the final rule. In addition, CR 12583 stated that 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)). 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, as noted in CR 12583.

Final Rule Action: After considering the comments and for the reasons discussed earlier in this section of this final rule, we are finalizing the changes to the descriptions of the ESRD PPS functional categories as proposed, as noted in the following Table 13. These changes will be effective January 1, 2023.

TABLE 13: Final 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 this 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 used 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.

C. 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, 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 would 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 would 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 would 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 would 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 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.[32] We finalized that this amount would 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)

[32] The CY 2021 TPNIES offset amount was $9.32. The CY 2022 TPNIES offset amount is $9.50. CMS is finalizing a CY 2023 TPNIES offset amount of $9.79, as discussed in section II.B.1.(e) of this final rule.

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)[33] 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.[34] PD therapy is a common cause of peritonitis.[35] If left untreated, the condition can be life threatening.[36] 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

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[33] 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)

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

[35] *Ibid.*

[36] *Ibid.*

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 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.[37] The applicant stated that only about 12 percent of eligible patients are on PD therapy.[38] 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/ℓL or > 0.1 x 10/L with polymorphonuclear (PMN) cells > 50 percent; and (3) positive dialysis effluent culture is identified.[39] 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.[40] Per the guidelines, this means

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[37] 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.
[38] Briggs, et. al., "Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution," unpublished report.
[39] 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.
[40] *Ibid.*

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 stated 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. We received no public comments on whether the CloudCath System meets this criterion. We consider the CloudCath System to be 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. We received no public comments on whether the CloudCath System meets this criterion. Based on the information provided by the applicant, we agree that the CloudCath System meets the newness criterion.

(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 will take effect, the applicant stated in its application that the CloudCath

System was not currently commercially available but noted that it expected the CloudCath System would be commercially available immediately after receiving FDA marketing authorization. In the CY 2023 ESRD PPS proposed rule (87 FR 38506), we stated that we did not have information as to whether the product became currently commercially available following the FDA marketing authorization on February 9, 2022. We solicited comment on the CloudCath System's commercial availability.

Comment: We received a comment from the applicant indicating that the CloudCath System has been commercially available to the U.S. population since July 2022. The applicant also provided a link to the CloudCath System's marketing materials.[41]

Response: Based on the information provided by the applicant, we agree that the CloudCath System meets the commercial availability criterion.

(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 a complete HCPCS Level II code application prior to the July 5, 2022 deadline. CMS received a HCPCS Level II application by the deadline and therefore, we agree the applicant has met the HCPCS Level II application criterion.

(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 made two claims. First, the applicant stated that the CloudCath System offers substantial clinical improvement over technologies currently available for the

[41] CloudCath, Remote Monitoring Platform for Catheter-Based Treatments. Available at: *https://www.cloudcath.com.* Accessed on September 8, 2022.

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 stated 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.[42] 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[43], which is not commonly used in the U.S. The remainder of the study participants were

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

[43] 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)

receiving Continuous Ambulatory Peritoneal Dialysis (CAPD).[44] The report states that in the U.S., PD is generally performed in a modality called Continuous Cycling Peritoneal Dialysis (CCPD)[45], 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/ɿL, > 50 percent PMN).[46] 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

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[44] 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)

[45] 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 2 1/2 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)

[46] 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.

In-Home Peritoneal Dialysis (CATCH).[47] 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.[48] Patients with active infection and/or cancer are excluded from the trial.[49] 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 x 109/L with percentage of PMN > 50 percent).[50] While the study is ongoing, the applicant included the study protocol and the first preliminary results with its application.[51] 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.[52]

Enrolled participants underwent an average of 4.5 dialysate exchanges per night.[53] 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.[54] According to the applicant, 5 of the 7 peritonitis events described in the CATCH study occurred after initial use of the CloudCath System, and all 5 of the peritonitis events were also detected by the CloudCath System.[55] In the 5 events, the CloudCath System detected peritonitis 44 to 368 hours prior to the

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[47] 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.
[48] 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.
[49] *Ibid.*
[50] *Ibid.*
[51] 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.
[52] *Ibid.*
[53] *Ibid.*
[54] *Ibid.*
[55] *Ibid.*

time of detection from a clinical laboratory.[56] 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.[57] 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.[58] 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.[59] 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.[60] 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.[61] 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.[62] However, neither symptom-to-contact nor symptom-to-treatment was

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[56] *Ibid.*
[57] *Ibid.*
[58] 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.
[59] *Ibid.*
[60] *Ibid.*
[61] *Ibid.*
[62] *Ibid.*

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 to effectively treat infections other than peritonitis.[63,64,65] 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 stated 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

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[63] 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.

[64] 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.

[65] 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.

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[66] 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 final 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

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[66] 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.

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, 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 stated, 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 Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38509 through 38510), after review of the information provided by the applicant regarding the CloudCath System, we noted the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1).

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, we stated that 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 noted previously in the CY 2022 ESRD PPS proposed rule (86 FR 36346 through 36347), it was 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 noted 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.[67] 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.[68] Because the studies submitted did not observe how patients and clinicians use the CloudCath System's monitoring to make decisions regarding patient management, we stated that it was 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).

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[67] 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.

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

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,[69] we stated that we had 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. We also noted 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 both the CY 2022 ESRD PPS proposed rule (86 FR 36346), and the CY 2023 ESRD PPS proposed rule (87 FR 38509) it was 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.[70] 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 noted 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

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[69] 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.

[70] 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.

peritonitis.[71,72] However, we noted 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.[73] In other words, we had 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.[74] 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 questioned 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 noted that we were 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. We requested information that demonstrates that the CloudCath System affects the management of the patient, including by impacting clinicians' diagnosis or treatment sequence.

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[71] 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.
[72] *Ibid.*
[73] 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.
[74] *Ibid.*

While the applicant updated the CY 2023 application to include more patient and site enrollment, CMS noted 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 stated in the CY 2023 ESRD PPS proposed rule that we welcomed 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 stated 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 expressed concern 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.[75,76,77] However, we noted that we did not receive any data demonstrating improved quality of life or PD retention with the use of the CloudCath System, and stated that we would be interested in additional evidence to support this claim.

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

We received multiple comments on the substantial clinical improvement claims made in the TPNIES application for the CloudCath System, ranging from commenters with concerns

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[75] 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

[76] 25 Ronco C, Crepaldi C, Rosner MH (eds): Remote Patient Management in Peritoneal Dialysis. Contrib Nephrol. Basel, Karger, 2019, vol 197, pp I–VI

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

about the applicant's claims to comments in support of the application, including those from the applicant, patients, clinicians, ESRD facilities and professional organizations. The comments on the substantial clinical improvement claims, and our responses to the comments, are set forth below.

Comment: We received a comment from the applicant in support of its application. The applicant included an updated analysis in support of its claim that the CloudCath™ System offers the ability to detect peritonitis earlier by more closely monitoring changes in turbidity of peritoneal dialysate effluent and provided responses to CMS concerns identified in the CY 2023 ESRD PPS proposed rule. We also received comments in support of the TPNIES approval from patients, clinicians, ESRD facilities, and professional organizations.

With respect to the applicant's first claim, that the CloudCath System offers substantial clinical improvement by offering the ability to detect peritonitis earlier by more closely monitoring changes in turbidity of peritoneal dialysate effluent, the applicant submitted an updated analysis of the CATCH study. Per the applicant, as of March 10, 2021, 12 individual participants experienced 14 peritonitis events meeting ISPD criteria. The applicant stated that the CloudCath System detected changes in all 14 peritonitis events of which 12 occurred after the initial use of the CloudCath System. The applicant further stated that two of the events occurred prior to the initial use of the CloudCath System and the CloudCath System detected changes in turbidity upon initial use. Per the applicant, of the 12 peritonitis events that occurred after the initial use, the CloudCath System detected the peritonitis events within a median of 108.42 hours prior to the time that clinical laboratory results became available and detected changes in turbidity within a median of 97.04 hours prior to the time that the patient presented to medical providers for peritonitis-related symptoms under current standard of care.

In response to CMS' concern that the studies submitted by the applicant do not observe how the CloudCath System affects the management of the patient, the applicant stated that since the CloudCath System enables clinicians to initiate, order and receive WBC count and

differential laboratory results days earlier, and subsequently initiate appropriate treatment days earlier than the current standard of care, this delta in diagnosis and treatment initiation time represents a significant positive change in patient management.

The applicant described a clinician work flow asserting that it would occur following a notification from the CloudCath System. Per the applicant, upon receiving a notification from the CloudCath System, a clinician should order a rapid WBC count and differential and that results would typically be available in 2 to 4 hours. The applicant stated that this would be considered the standard diagnostic workup for patients suspected of peritonitis before starting antimicrobial treatment. The applicant further clarified that the CloudCath System is not intended to be used as a replacement to bypass the need for laboratory diagnostics. The applicant further noted that if the results from the WBC count and differential return WBC > 100/uL with >50% polymorphonuclear leukocytes (PMN,) clinicians would have confidence to proceed with initiating antimicrobial treatment. As such, the applicant stated that the use of the CloudCath System would not result in any more unnecessary antimicrobial use than would occur with the current standard of care guidelines to initiate antibiotic treatment solely based on the presentation of cloudy effluent.

The applicant also surveyed 18 physicians who confirmed via a consensus affidavit the anticipated workflow described by the applicant; the conclusion that the use of the CloudCath System would not result in increased unnecessary antimicrobial treatment; and that the use of the CloudCath System is expected to result in a positive change in patient management.

We received several supporting comments from clinicians and a trade association regarding use of the CloudCath System as a monitoring system. Several physician commenters shared their experience with the CloudCath System, stating that the notification from the CloudCath System would allow them to achieve an earlier diagnosis by verifying the CloudCath System's results with results of peritoneal fluid cell counts and differentials before initiating antimicrobial treatment. A trade association stated that because of the severity of patient risk

from peritonitis, current clinical guidelines provide physicians with flexibility to prescribe antibiotic treatment without advance receipt of a positive antibody cell culture, if other signs and symptoms are present. A physician commenter stated that an elevated turbidity score from the CloudCath System would help clinicians make empiric antimicrobial treatment decisions as early as possible while results of peritoneal fluid cell counts and differentials are pending. This same commenter noted that the practice would not increase antibiotic use as it falls in line with the way that other suspected infections are treated like bacteremia and urinary tract infections according to current sepsis guidelines.

With regard to the concern about whether use of the CloudCath System has demonstrated improved clinical outcomes, including lower hospitalization rates, an increase in the use of PD, a decrease in PD modality loss, or improved mortality, the applicant claimed that studies have shown the benefits of home dialysis compared to in-center HD, such as survival, quality of life, decreased transportation costs, increased patient autonomy and clinical benefits such as enhanced blood pressure and phosphorus control. The applicant cited a study by Uchiyama et al. highlighting the ability of remote patient monitoring in patients undergoing automated PD to reduce cost, disease burden, clinical resources, hospitalizations, technique failures as well as improved treatment adherence and blood pressure control.[78] The applicant stated that prioritizing PD is beneficial for patients, providers and payers in light of the findings that more frequent dialysis in the home setting is associated with improved clinical outcomes, such as improvement in blood pressure control with fewer antihypertensive medications, volume management, left ventricular hypertrophy, phosphate control, and fewer hospital days and

[78]Uchiyama, Kiyotaka et al. Effects of a remote patient monitoring system for patients on automated peritoneal dialysis: a randomized crossover controlled trial. International urology and nephrology, 1–9. 1 Apr. 2022, doi:10.1007/s11255-022-03178-5.

hospitalizations.[79, 80, 81, 82] The consensus affidavit supported the claim that the CloudCath System is expected to result in a significant clinical improvement in outcomes related to patient survival and sustained use of the PD modality.

With regard to the concern that there may be insufficient evidence to demonstrate that the CloudCath System improves patients' quality of life, the applicant stated that at-home PD has been shown to improve health-related quality of life because it can be administered in the comfort of the patient's own home, commonly when they are sleeping rather than during the day such as in the case of in-center HD. The applicant further claimed that for many patients, this improves their quality of life by allowing them to remain in the workforce.

Several commenters expressed appreciation for the CloudCath System's remote continuous monitoring feature. Individuals identifying as patients and clinicians stated that knowing that there is a system providing continuous monitoring support would give patients and the clinical team more confidence in patient oversight for PD than the current standard of care. Patient commenters stated that their healthcare providers would have the ability to react to peritonitis and other complications faster with the notification from the CloudCath System than if they were to monitor signs and symptoms by themselves.

Response: We thank the applicant and other commenters for their input and have taken this information into consideration in our determination of whether the CloudCath System meets the TPNIES eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the CloudCath System at the end of this section of the final rule.

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[79] Walker, Rachael C et al. Home hemodialysis: a comprehensive review of patient-centered and economic considerations. ClinicoEconomics and outcomes research : CEOR vol. 9 149-161. 16 Feb. 2017, doi:10.2147/CEOR.S69340

[80] Yu, Xueqing et al. Shared Decision-Making for a Dialysis Modality. Kidney international reports vol. 7,1 15-27. 30 Oct. 2021, doi:10.1016/j.ekir.2021.10.019

[81] Cozzolino, Mario et al. COVID-19 pandemic era: is it time to promote home dialysis and peritoneal dialysis?. Clinical kidney journal vol. 14,Suppl 1 i6-i13. 2 Feb. 2021, doi:10.1093/ckj/sfab023

[82] Lockridge, Robert Jr et al. A Systematic Approach To Promoting Home Hemodialysis during End Stage Kidney Disease. Kidney360 vol. 1,9 993-1001. 8 Jul. 2020, doi:10.34067/KID.0003132020

Comment: A commenter, a dialysis product and service provider, stated that the evidence presented in the TPNIES application for the CloudCath System does not meet the substantial clinical improvement criterion. In referring to the evidence provided by the applicant, including the Briggs et al. study[83] and the CATCH study,[84] the commenter stated that the applicant had not presented evidence showing how use of the CloudCath System to detect peritonitis affects the management of the patient, as is required by the substantial clinical improvement criterion. For example, the commenter stated that in the CATCH study, neither the investigators nor subjects were aware of the CloudCath System's measurements and no clinical decision making was based upon readings from the CloudCath System. The commenter further stated that in the Briggs et. al. study, the authors comment that none of the data from the device was used for clinical decision-making, which indicates that the study did not test how or if the CloudCath System offered the ability to diagnose a medical condition more rapidly and how use of the CloudCath System to make a diagnosis affected the management of the patient.

The commenter also expressed concern regarding the Briggs et al. study, in which a large number of samples were false positives including already being on antibiotics for peritonitis as well as causes other than peritonitis. The commenter further stated that such a high false positive rate and the need to exclude patients already receiving treatment for peritonitis, who might have a resistant infection, could lead to inappropriate prescribing of antibiotics, increasing the risk of secondary infections or fungal infections.

The commenter also expressed concerns with the applicant's claims that patients with a false positive for infection would not have received inappropriate use of antimicrobial therapy compared to the standard of care per ISPD guidelines. The commenter noted that if this were the

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

[84] 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.

case with the CloudCath System, then earlier intervention with antimicrobial therapy would never occur if the patient had not yet met at least 2 of the ISPD diagnostic criteria. As such, the commenter concluded that CloudCath does not have sufficient evidence that it offers substantial clinical improvement to the current standard of care.

The commenter stated that there is no evidence that use of the CloudCath System would decrease future hospitalizations or physician visits or lead to a more rapid beneficial resolution of the disease process. The commenter stated that the Muthucumarana et al. study[85] submitted by the applicant was not related to the CloudCath System and no data or evidence was provided that demonstrated that the CloudCath System would reduce time to treatment in patients.

Response: We appreciate the commenters' input regarding whether the CloudCath System meets the TPNIES innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1).

We acknowledge that the updates to the CATCH study submitted by the applicant provide additional evidence that the CloudCath System identifies nearly every case where peritonitis was ultimately diagnosed. While these additional cases did not include clinical vignettes, the patient presentations from earlier cases were reassuring that identified cases represent true instances of peritonitis. The finding that changes in turbidity were identified by the CloudCath System within a median of 97.04 hours prior to the time that the patient presented to medical providers for peritonitis-related symptoms suggests that the CloudCath System has the potential to produce an earlier diagnosis of peritonitis. We agree that early diagnosis is important because, as referenced by the applicant in the PROMPT study, each hour of delay in treating peritonitis is associated with 7% increased risk of PD failure and patient death. We also

[85] 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.

agree that the prevention of severe infection could lead to improved health outcomes and, for some patients, the ability to remain on peritoneal dialysis for longer.

We understand from input provided by clinician commenters that clinicians might use the CloudCath System in place of clinical signs and symptoms of peritonitis when assessing for possible peritonitis and that many clinicians would not initiate antibiotics until peritonitis is confirmed through a cell count and differential of peritoneal fluid. CMS agrees that the use of the CloudCath System in this way would limit the potential for unnecessary antibiotic treatments due to false positive readings, although unnecessary laboratory testing with cell counts in otherwise asymptomatic patients might still result from high false positive rates. The applicant asserts, without study data, that the use of the CloudCath System would not result in any more unnecessary antimicrobial use than would occur with the current standard of care ISPD guidelines to initiate antibiotic treatment.

We appreciate comments pertaining to patient experiences and the way in which monitoring via the CloudCath System may reassure patients and providers. We also acknowledge the information about the ways in which peritoneal dialysis improves quality of life, reduces the use of health care resources, improves health outcomes, and offers patients with autonomy, but note the absence of data demonstrating that the CloudCath System helps patients to continue using peritoneal dialysis.

CMS is supportive of new and innovative supplies and equipment for renal dialysis services. However, we remain concerned that there is no evidence, as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B), that using the CloudCath System affects the management of the patient in a way that improves the diagnosis and treatment of peritonitis. Current evidence is mainly based off proof of principle studies. Despite new updates to the CATCH study, we note that, similar to previously reported findings, the updates do not include evidence that peritonitis was actually diagnosed or acted on sooner by clinicians. Importantly, the findings do not include information about whether the detection of peritonitis by

the CloudCath System led to improvements in key health outcomes required for demonstrating substantial clinical improvement. Any additional data provided is still limited by the overall study design.

The applicant has not provided clear evidence that using the CloudCath System affects the management of the patient by reducing time-to-treatment. With the CloudCath System alarm turned off, the studies did not evaluate patient or clinician behavior resulting from information generated by the CloudCath System. In the Briggs et al. study, CloudCath data was not used for clinical decision making. Similarly, in the CATCH study, neither participants nor investigators were aware of the CloudCath System's measurements. There are no studies addressing outcomes such as hospitalizations, resolution of disease process, or healthcare use. While the PROMPT study refers to the dangers of a delay in treating peritonitis, it did not evaluate the CloudCath System.

We acknowledge that the applicant, clinician affidavit, and other commenters provided input on how the CloudCath System *could be used* in a clinical setting. While clinician commenters offered input about the way in which clinicians might manage a patient following a CloudCath System notification, commenters provided multiple conflicting reports of how clinicians would use the technology. Comments from clinicians indicate a varied response: some may treat a patient empirically based on turbidity findings, while others may wait for rapid cell counts if available.

In light of the first response (treating empirically based on turbidity), possible harm from the presence of false positives remains a serious concern. The applicant's submitted evidence does not convincingly refute the concern of possible false positives from the CloudCath System. Thus, clinicians who choose to prescribe antibiotics without waiting for confirmatory diagnostic tests such as a cell count have the potential for overprescribing antibiotics. Using the technology to make decisions about empiric treatment, might be especially likely to occur when patients

cannot come to the dialysis unit for a peritoneal fluid collection or when laboratory results are not expedited.

We remain concerned that if there is a high false positive rate, the device may inequitably result in certain vulnerable populations disproportionately receiving inappropriate antibiotics. In particular, beneficiaries living in underserved areas may not have access to a rapid cell count or quick turnaround of other confirmatory tests and could be particularly vulnerable to the potential harm of treating false positives. Clinicians in underserved areas may not have access to rapid cell counts and patients in these areas may be less likely to access rapid cell counts except through an Emergency Department. As such, more information about false positivity would be beneficial to better understand the ramifications of practice changes, and whether clinical benefits from more rapid detection outweigh costs from false positives. We note that demonstration of a low false positive rate could offset concerns for inappropriate antibiotic use, especially in underserved areas where rapid cell counts may not be available. As such, a low false positive rate is more likely to improve health equity.

We acknowledge that many clinician commenters stated that they would not initiate empiric antibiotics without confirmatory testing. However, for these situations, the applicant did not present evidence that the CloudCath System would result in a quicker diagnosis or treatment of peritonitis. It is also unclear how much sooner patients would present to a healthcare provider in response to a positive CloudCath System reading when compared to traditional signs and symptoms of peritonitis. Evidence of clinician behavior, meaning data that captures the way in which the CloudCath System's notifications affect the management of the patient in the clinical setting, would help to address these uncertainties.

Finally, we appreciate the patient letters describing the risks and anxieties of venturing out on home dialysis, mostly without the clinician oversight or accessibility that would be available to patients dialyzing in-center. While there is potential for the CloudCath System to improve quality of life by providing an added level of assurances, the applicant has not provided

supporting evidence to demonstrate improvements in quality of life, which per § 412.87(b)(1)(ii)(C)(6), is one way that a new technology can demonstrate substantial clinical improvement.

After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2023 ESRD PPS proposed rule, as well as the many comments submitted by the public, we have determined that the CloudCath System has not shown that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. Therefore, we conclude that the CloudCath System does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(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 noted in the CY 2023 ESRD PPS proposed rule 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[86] and we received no public comments on this criterion.

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that the CloudCath System meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, the CloudCath System will not be paid for using the TPNIES per § 413.236(d).

We note that in the CY 2021 ESRD PPS final rule (85 FR 71412), CMS indicated that entities would have 3 years beginning on the date of FDA marketing authorization in which to

[86] 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

submit their applications for the TPNIES. Based on the CloudCath System's FDA marketing authorization date of February 9, 2022, the applicant is eligible to apply for the TPNIES for CY 2024, CY 2025, or CY 2026, and CMS will review any new information provided for the particular CY rulemaking cycle.

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 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 service that is furnished to individuals for the treatment of ESRD and essential for the delivery of maintenance dialysis. We received no public comments on whether the SunWrap™ System meets this criterion. We consider the SunWrap™ System to be 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.[87]

As we discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38511), 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.[88] 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.[89]

After a review of the information provided by the applicant, in the proposed rule, we noted the following concerns with regard to the newness criterion under § 413.236(b)(2). Consistent with § 413.236(c), we stated that CMS would 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.

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[87] 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.

[88] 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.

[89] 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.

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 requested 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 noted 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 noted 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.[90] 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 welcomed public comment on these issues.

Comment: One commenter agreed with CMS regarding the lack of clarity as to which of

[90] 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 7, in the family of the SunWrap™ System products, are the subject of the CY 2023 TPNIES application and with regard to the lack of a date that the product received Class 1 Exempt status. The commenter also stated that the newness criterion delineates FDA marketing authorization as a requirement to apply for the TPNIES and that for CMS to extend the eligibility criterion beyond technologies with FDA marketing authorization (that is, Class I Exempt status) would require future rulemaking. The commenter stated that CMS should clarify in future rulemaking whether devices that are considered FDA Class I Exempt are eligible for the TPNIES.

Response: We thank the commenter for their comments regarding the newness criterion. We did not receive additional information from the applicant pertaining to our newness concerns. Therefore, it remains unclear as to which of the SunWrap™ System products are the subject of the TPNIES application. We also note that as indicated in the CY 2023 ESRD PPS proposed rule, devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy for the devices. We maintain that our intent in requiring applicants to receive FDA marketing authorization was to exclude devices that lack FDA marketing authorization (87 FR 38511). Therefore, in the absence of evidence that the technology is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the SunWrap™ System does not meet the TPNIES newness criterion under § 413.236(b)(2).

(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 SunWrap™ System is currently commercially available. While we received no public comments on this criterion, and we continue to have questions about which of the 7 products are the subject of the TPNIES application, the SunWrap™ System appears to meet the commercial availability criterion.

(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. We received no public comment on whether the SunWrap™ System meets this criterion, however CMS received a HCPCS Level II application by the deadline. Therefore, we agree the applicant has met the HCPCS Level II application criterion.

(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), as discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38511 through 38513), the applicant stated 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, 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.[91]

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.[92] The applicant also stated that the SunWrap™ System reduces the need for revascularization due to stenosis/thrombosis.[93]

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

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[91] **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.
[92] **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.
[93] Ibid.

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),[94] case studies on fatal hemorrhage from HD vascular access sites,[95] and a case study of managing fistula complications in the Emergency Department.[96] The applicant stated that there are 786,000 annual ESRD patients, 71 percent are on dialysis and 29 percent have kidney transplants.[97] 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.[98] The applicant also stated that a review of standard and

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[94] 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.

[95] 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.

[96] **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.

[97] 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.

[98] 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.

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.[99] 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 stated 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

[99] 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

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. 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 noted in the CY 2023 ESRD PPS proposed rule 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 stated that the dialysis may have been the major contributing factor for the thrombosis.

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

After a review of the information provided by the applicant, in the CY 2023 ESRD PPS proposed rule, we noted the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1).

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. We stated that it will be helpful for our evaluation if the applicant will 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 noted 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 questioned the extent to which this data would be generalizable to the ESRD facility setting and stated that we 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 noted 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 requested 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 stated that 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, we stated that 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 final rule, the applicant provided a listing of 7 SunWrap™ System products. We requested clarification as to which of the 7 SunWrap™ System products were included in the primary pilot study of 54 patients. We welcomed public comment on these issues.

Comment: We received several public comments regarding the substantial clinical improvement claims made in the TPNIES application for the SunWrap™ System. While one commenter offered general support of all technologies being considered for CY 2023 TPNIES, including the SunWrap™ System, the remaining commenters expressed concerns.

A few commenters stated that direct clinical evidence was not provided to support the applicant's claims of substantial clinical improvement. One commenter emphasized that each claim of substantial clinical improvement should be directly linked to supporting evidence.

With respect to CMS' concern regarding the absence of data pertaining to the use of the SunWrap™ System in the ESRD facility setting, commenters agreed that specific data pertaining to the use the SunWrap™ System for the purpose of controlling bleeding at the needle puncture sites following HD in the ESRD facility setting would be needed to establish substantial clinical improvement. One commenter questioned whether the unpublished single pilot study would support the technology's intended use as a renal dialysis service given that it does not involve the use of the SunWrap™ System following HD treatment in the ESRD facility setting.

One commenter stated that human holding of the needle site is the standard of care and allows variable pressure post needle removal, and that the SunWrap™ System does not allow for this variable adjustment. One commenter stated that patients who attempted to use the device

post dialysis, experienced excessive bleeding. Another commenter stated the two cases of post-operative bleeding and four cases of thrombosis resulted in a complication rate of 11.1 percent. compared to a more typical rate of 1.7 percent, and expressed concern that the SunWrap™ System potentially predisposes patients to greater risk of thrombosis after its use.

Response: We appreciate the input provided by the commenters and agree that there is a lack of evidence that the SunWrap™ System controls bleeding at the needle puncture sites following HD in the ESRD facility setting. We also agree with the comments expressing uncertainty as to whether the use of the SunWrap™ System predisposes patients to greater risk of thrombosis after its use. Because we did not receive a public comment from the applicant addressing our concerns set forth in the CY 2023 ESRD PPS proposed rule (87 FR 38513), those concerns also remain. First, it is not clear whether the technology is indicated for use limited to patients with AV fistula access sites or if it is also indicated for use among patients with AV graft access sites. Second, it is unclear which of the 7 SunWrap™ System products were included in the primary pilot study. Finally, we did not receive evidence that the SunWrap™ System met patient satisfaction and safety requirements after multiple trials nor did we receive data comparing the SunWrap™ System's outcomes to outcomes of patients treated by manual compression at the puncture site following HD. Therefore, we conclude that the SunWrap™ System does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(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. We received no public comments on this criterion. 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.[100]

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that the SunWrap™ System meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, the SunWrap™ System will not be paid for using the TPNIES per § 413.236(d).

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 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. As we noted in the CY 2023 ESRD PPS proposed rule, 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 PPS final rule (85 FR 71444 through 71457).[101]

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[100] 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

[101] 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).

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.[102] 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.[103,104,105] 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 stated 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.[106]

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

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[102] Baxter. Theranova 400/500 Instructions For Use. N50 648 rev 003, 2017-05-29.
[103] 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
[104] Stenvinkel P. Can treating persistent inflammation limit protein energy wasting? Semin Dial. 2013;26(1):16-19. doi:10.1111/sdi.12020
[105] Akchurin OM, Kaskel Fl. *Update on inflammation in chronic kidney disease.* Blood Purif 2015; 39:84- 92.
[106] 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

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). While we received no public comments on whether THERANOVA meets this criterion, a dialyzer would be considered a supply essential for the delivery of maintenance dialysis and, therefore, we will consider THERANOVA to be 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. We received no public comments on whether the THERANOVA meets the newness criterion. Based on information provided by the applicant, we agree that THERANOVA meets the newness criterion.

(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. We received no public comments on whether the THERANOVA meets this criterion. Based on the information provided by the applicant, THERANOVA meets the commercial availability criterion.

(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. The applicant also

indicated that it submitted a HCPCS Level II application for THERANOVA by the July 5, 2022, deadline. We received no other public comments on whether THERANOVA meets this criterion, however, we received a HCPCS Level II application by the deadline. Therefore, we agree the applicant has met the HCPCS Level II application criterion.

(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 stated that THERANOVA significantly improves clinical outcomes relative to the current standard of care for dialysis membranes. As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38513 through 38520), 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,[107] with roughly 40 percent of new dialysis patients averaging nearly two hospitalizations per year.[108] The applicant also stated that ESRD patients often have health impairments associated with their condition and other comorbidities that put them at greater risk for 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.[109] 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[110] 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

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[107] 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.

[108] 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.

[109] 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

[110] 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

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).[111]

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.[112]

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,

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[111] 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.

[112] 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.

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 stated 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).[113]

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),[114] 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 stated 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

[113] 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
[114] Ibid

that the results showed that HDx was statistically significantly associated with reduced hospitalization days.[115]

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 of rest or sleep. The applicant cited an estimate that 40 to 80 percent of patients receiving chronic HD face post-dialysis fatigue.[116] The applicant also noted that patients who were highly fatigued had a significantly higher risk of adverse cardiovascular events (hazard ratio: 2.17; $p < 0.01$).[117] 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).[118] 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

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[115] 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

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

[117] 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

[118] 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

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; $p = 0.001$).[119]

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 stated that pruritus that is severe or chronic can prevent ESRD patients from sleeping normally,[120] and that in addition to causing sleep loss, pruritus can also cause anxiety and depression.[121] The applicant

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[119] 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.S 325016

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

[121] Ibid

also noted that prolonged scratching of itchy skin also leads to skin injury, scarring, and infection.[122]

The applicant also explained that one of the most commonly used tools to assess kidney disease QoL in the U.S. is the KDQoL[123] 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.[124]

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

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[122] Ibid
[123] RAND Corporation, Kidney Disease Quality of Life Instrument (KDQOL), available at https://www.rand.org/health-care/surveys_tools/kdqol.html
[124] 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.

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.[125]

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 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 stated 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).

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[125] 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

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; $p < 0.001$).[126]

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,[127] with one study suggesting 20 to 25 percent of ESRD patients demonstrated overt (moderate to severe) RLS.[128] The applicant stated that extreme discomfort of RLS worsens during periods of physical inactivity and at night,[129] 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.[130] 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.[131] 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

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[126] 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.2 021.05.010
[127] Kavanagh D, et al. Restless legs syndrome in patients on dialysis Am J Kidney Dis. 2004 May;43(5):763-71.
[128] Winkelman JW, Chertow GM, Lazarus JM. Restless legs syndrome in end-stage renal disease. Am J Kidney
[129] Kavanagh D, et al. Restless legs syndrome in patients on dialysis Am J Kidney Dis. 2004 May;43(5):763-71.
[130] 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.
[131] Lin CH, 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.

of which produce side effects and only provide limited improvement in RLS symptoms.[132] 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.[133]

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: $p = 0.003$).[134]

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.[135] 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

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[132] Gopaluni S, Sherif M, Ahmadouk NA. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690
[133] Gopaluni S, Sherif M, Ahmadouk NA. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690
[134] 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.
[135] Mayo Clinic's overview of anemia, available at https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360.

blood cells. The applicant stated 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.[136] The applicant stated that reductions in iron treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.[137]

Finally, with regard to insulin use, the applicant stated that diabetes is a common comorbidity in ESRD patients,[138] and many ESRD patients require additional insulin administration. The applicant stated that through reductions in insulin use, Medicare could realize cost savings of $3,949 annually per diabetes patient.[139]

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).[140] 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,

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[136] Fishbane S, Maesaka JK, 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.

[137] 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%

[138] 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.

[139] 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/

[140] 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

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 [µg/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.[141]

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 ($p = 0.0361$).[142] 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 ($p = 0.003$).[143]

Finally, the applicant referred to the Ariza et al. (2021) study, described previously in this section of the final 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; $p < 0.01$).[144] The applicant also stated 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; $p < 0.01$).[145]

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[141] 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

[142] 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

[143] Ibid

[144] 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

[145] Ibid

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.[146] 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 stated that with the updated and additional information provided in its CY 2023 application, the applicant has addressed these concerns.

The applicant stated 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,[147] and Alarcon et al., n = 992,[148] previously described. The applicant explained that additionally, many studies evaluated THERANOVA's impacts over an extended period,

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[146] 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.

[147] 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.

[148] 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.

including year-long evaluations after patients transitioned from conventional therapy to HDx therapy, for example, Sanabria et al.[149] and Ariza et al.,[150] 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 stated 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 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;[151] 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 stated that the peer-validated studies, and

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[149] 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

[150] 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

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

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.[152] 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 Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2023 ESRD PPS proposed rule (87 FR 38513), we noted 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

[152] 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

application,[153,154,155,156,157,158] and the remaining evidence submitted with the CY 2023 application was new. We identified the following concerns regarding THERANOVA and the substantial clinical improvement eligibility criteria for the TPNIES.

With respect to the applicant's claim that THERANOVA leads to reduced hospitalization rates, we noted that the applicant included studies from the previous submission and supplemented with newer studies, such as the Tran et. al. (2021) poster abstract. We noted that the poster abstract was a post hoc analysis of a previous open-label study,[159] which had an average follow-up period of 4.5 months in the THERANOVA group. We questioned whether this short time period is sufficient to see changes in hospitalization from interventions aimed at increasing clearance of uremic toxins. We stated that it may be helpful to see if this outcome is sustained in longer term follow-up.[160]

We also noted 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 noted that patients seemed healthier in the THERANOVA arm, and had more fistulas, fewer catheters, and higher Karnofsky indices. We also noted that the THERANOVA arm had more intensive dialysis at

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[153] 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.
[154] 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
[155] 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.S 325016
[156] 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
[157] 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
[158] 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
[159] 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
[160] 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.

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, we stated that it is unclear whether the outcome differences between the two arms could be due to factors other than the dialyzer type. We questioned whether IPTW would be sufficient to overcome these biases, especially the Kt/V bias, which persisted even after the baseline period.[161]

In addition, we noted that the studies by Ariza et. al. (2021)[162] and Sanabria et. al. (2021),[163] 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 (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 noted 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 noted 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 noted 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).[164]

Overall, we noted 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 noted

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[161] 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.

[162] 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

[163] 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

[164] 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

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.[165,166,167,168]

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

We received many comments on the substantial clinical improvement claims made in the TPNIES application for THERANOVA, ranging from commenters with concerns about the claims, including clinicians and dialyzer companies, to comments in support of the application from clinicians, patients, and the applicant. The comments pertaining to the substantial clinical improvement claims made by the applicant, and our responses to the comments, are set forth below.

Comment: We received a comment from the applicant in support of the TPNIES approval for THERANOVA. The applicant reiterated its substantial clinical improvement claims; submitted additional evidence in support of its claims; provided responses to CMS concerns identified in the CY 2023 ESRD PPS proposed rule; and included a discussion pertaining to albumin loss associated with THERANOVA.

In reiterating its substantial clinical improvement claims, the applicant stated that THERANOVA demonstrated reduced hospitalization rate by up to 45%, improved recovery time by up to 2 hours, improved quality of life in two Kidney Disease Quality of Life (KDQoL) survey domains, reduced pruritus, demonstrated improvement in London Evaluation of Illness

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[165] 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.S 325016

[166] 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.2 021.05.010

[167] 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.

[168] 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

(LEVIL) survey scores, reduced prevalence of restless leg syndrome, reduced the need and use of erythropoietin stimulating agents (ESAs), reduced the need for iron, and reduced the need for insulin.

The applicant submitted additional evidence, including a peer-reviewed article by Blackowicz et al.,[169] that was a follow-on to the Tran et al. abstract[170] to demonstrate a statistically significant lower hospitalization rate in the cohort using THERANOVA compared to the cohort using a high flux dialyzer (IRR = 0.55; p = 0.042). The applicant noted that this new study affirms the initial findings in the Tran et al. abstract[171], determining that the all-cause hospitalization rate was 45% lower with THERANOVA as compared to HD with a high-flux dialyzer (IRR = 0.55; p = 0.042). The applicant also noted a $6,098 lower average annual cost of hospitalization for the THERANOVA group compared to the conventional high-flux dialyzer group.

The applicant submitted a peer-reviewed follow-on[172] to the Molano-Triviño et al. abstract[173] stating that it found a statistically significant lower hospitalization rate in the THERANOVA group compared to the high-flux dialyzer group. The applicant stated its belief that this new study affirms the initial findings in the Molano-Triviño abstract and confirms the reduced hospitalization rate finding.

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[169] Blackowicz MJ, Falzon L, Beck W, Tran H, Weiner DE. Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States. Hemodial Int. 2022 Jul;26(3):449-455. doi:10.1111/hdi.13015. Epub 2022 Apr 19. PMID: 35441486.

[170] 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.

[171] 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.

[172] Molano A, et al. Medium Cutoff Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Med. 4(4):100431. Published online February 7, 2022. Doi:10.1016/j.xkme.2022.100431

[173] Molano-Triviño A, Sanabria M, Vesga J, Buitrago G, Sánchez R, Rivera A. MO880: Effectiveness of Medium Cut- Off vs. High Flux Dialyzers: A Propensity Score Matching Cohort Study, Nephrology Dialysis Transplantation, Vol. 36, Issue Sup. 1, 2021, May. gfab100.005, https://doi.org/10.1093/ndt/gfab 100.005

In response to the CMS question of whether the average follow-up period of 4.5 months is sufficient to see changes in hospitalization**,** the applicant stated that Blackowicz et al.[174] affirmed findings in the Tran et al. abstract[175] and stated that if the study had not been long enough, it would not have reached statistical significance on the hospitalization rate endpoint. The applicant also stated that the ability of the study to detect a statistically significant difference in hospitalization events throughout the study period suggests a sufficiently large magnitude of effect in hospitalization events and that a study with longer follow-up periods would likely affirm this difference in hospitalization rates.

The applicant described an ongoing prospective interventional control trial currently being conducted in Canada to assess THERANOVA's impact on patient quality of life versus HD with a high flux dialyzer.[176] The applicant stated that the investigator expanded the trial and is currently recruiting U.S. participants. The primary outcomes assessed are changes in symptoms burden and health-related quality of life (HRQoL) using a dynamic patient-reported outcome measurement (PROM) tool [London Evaluation of Illness (LEVIL)]. Patients receiving HD with a high-flux dialyzer at baseline are switched to THERANOVA and assessed at regular intervals. The applicant stated that 48 patients are enrolled in the Canadian arm and also outlined preliminary results. The applicant stated that when comparing baseline measurements using a high flux dialyzer to THERANOVA at the three-month interval, the investigator's preliminary analysis shows a statistically significant improvement in overall HRQoL ($p = 0.03$), energy levels ($p = 0.006$), sleep quality ($p = 0.003$) and pruritus ($p = 0.008$). Additionally, 83 percent of the study population had a 10 percent or greater directional improvement in at least

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[174] Blackowicz MJ, Falzon L, Beck W, Tran H, Weiner DE. Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States. Hemodial Int. 2022 Jul;26(3):449-455. doi: 10.1111/hdi.13015. Epub 2022 Apr 19. PMID: 35441486.
[175] 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.
[176] NCT03640858; clinicaltrials.gov

one of 11 symptom domains studied, including 'recovery time,' 'energy,' 'pruritus,' 'sleep quality,' 'general well-being,' 'bodily pain,' and 'restless leg syndrome.'

In response to the CMS concern regarding Lim et al.,[177] as to whether the quality of life improvement findings could result from chance alone due to multiple-hypothesis testing, the applicant stated that the study analyzed all KDQoL domains validated in the literature and that comprehensive statistical analysis of all the individual KDQoL domains must contend with similar potential multiple-hypothesis testing concerns.

In response to the CMS concern regarding Lim et al.,[178] regarding the non-significant difference in afternoon pruritus distribution, the applicant stated that quality of life improvement findings, including improvement in two KDQoL survey domains and reduced morning pruritus distribution, are supported by findings in Penny et al.[179] which achieved high levels of significance (for example, $p < 0.001$), suggesting that these results would remain statistically significant even after applying a correction for multiple hypothesis testing.

In response to the CMS concern regarding differences in baseline characteristics of the two groups in Molano et al.,[180] the applicant stated that the study employed inverse probability of treatment weighting (IPTW) which re-adjusts characteristics across the two groups to increase similarities and mitigate differences and that FDA recognizes the utility of inverse probability weighting as a statistical method to control for potential bias.

In response to the CMS concern regarding the design of several studies included in the THERANOVA application, the applicant stated that observational study designs inform how

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[177] 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

[178] 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

[179] 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.2 021.05.010.

[180] Molano-Triviño A, Sanabria M, Vesga J, Buitrago G, Sánchez R, Rivera A. MO880: Effectiveness of Medium Cut- Off vs. High Flux Dialyzers: A Propensity Score Matching Cohort Study, Nephrology Dialysis Transplantation, Vol. 36, Issue Sup. 1, 2021, May. gfab100.005, https://doi.org/10.1093/ndt/gfab 100.005

interventions work in a real-world setting and provide results with a larger sample size and greater generalizability to the target patient population over a longer period of time. The applicant also noted that conducting randomized control trial (RCT) studies in the ESRD patient population remains a continuing challenge and that major RCT studies conducted in dialysis populations run into challenges due to unexpectedly low event rates and high dropout and crossover rates. The applicant stated that these challenges make it difficult to generate large enough sample sizes to establish efficacy for RCT study designs within dialysis populations and that there is a risk that randomization does not evenly distribute observable characteristics without large enough sample sizes.

In support of its data with historical controls, the applicant stated that self-controlled case studies (SCCS), whereby individuals act as their own control, could be used to generate statistical inferences with relatively small sample sizes and are effective for highly complex and heterogenous patient populations, like patients with ESRD who have multiple comorbidities. The applicant stated that an SCCS provides an opportunity to control for unobservable characteristics in a real-world setting, as long as time does not serve as a confounding characteristic since the same patient serves as control and treatment. The applicant reiterated that supporting evidence from SCCS studies in the CY 2023 THERANOVA TPNIES application is a significant strength, given the sustained improvements over time, as ESRD patients typically have a rapidly deteriorating health profile and that similar results were found in multiple SCCS studies, in different environments and at different times making it very unlikely that unobservable confounders might be credited with the observed change.

Finally, the applicant referred to FDA affirmation that THERANOVA is safe and effective for its intended use. Per the applicant, studies, such as Molano et al.[181] show no difference in serum albumin levels for THERANOVA compared to high-flux dialyzers and that a

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[181] Molano A, et al. Medium Cutoff Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Med. 4(4):100431. Published online February 7, 2022. Doi: 10.1016/j.xkme.2022.100431

randomized controlled study showed that the albumin loss associated with THERANOVA is considerably less than the transperitoneal albumin losses seen in peritoneal dialysis.[182]

We also received many comments from clinicians and patients supporting the THERANOVA application for TPNIES for CY 2023. Some comments from individuals identifying as patients noted improved energy associated with the use THERANOVA and expressed a general desire for more innovative products and concerns in paying for the dialyzer. Other comments were from individuals identifying as clinicians providing general support, expressing a desire for more innovation, and reiterating evidence and data from the application.

Response: We thank the commenters for their input and have taken this information into consideration in our determination of whether THERANOVA meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for THERANOVA at the end of this section of the final rule.

Comment: We received many comments from clinicians and dialyzer companies with concerns about the applicant's substantial clinical improvement claims. One commenter described weaknesses in the evidence that was used to support the applicant's claims of improved recovery time, improved quality of life, and reduced restless leg syndrome. The commenter reiterated and supported CMS' earlier concerns about quality of evidence. The commenter highlighted the studies by Bolton et al., Lim et al., Alarcon et al., Sanabria et al., and

[182] Kirsch AH, Lyko R, Nilsson LG, et al. Performance of hemodialysis with novel medium cut-off dialyzers [published correction appears in Nephrol Dial Transplant. 2021 Jul 23;36(8):1555-1556]. Nephrol Dial Transplant. 2017;32(1):165-172. doi:10.1093/ndt/gfw310

Ariza et al., [183, 184, 185, 186, 187] noting that they were small in size, retrospective, had high withdrawal rates, based on a single-site, unblinded, uncontrolled, occurred outside the U.S., had Type I errors, and/or short-duration. Specifically, with Bolton et al., the commenter stated that it is also unclear when medium cutoff membrane dialyzers replaced high flux dialyzers as the standard of care and if the comparison was appropriate.

The commenter also stated that with regard to quality-of-life outcomes, there was no difference in the Palliative Care Outcome Scale Symptoms Renal total symptom score at 12 months in poor mobility, difficulty sleeping, pain, shortness of breath, drowsiness, restless legs, skin changes, constipation, poor appetite or diarrhea. The commenter also stated that the Lim et al. study did not analyze change from baseline. The commenter stated that because the Weiner et. al. study was the only randomized control trial of health-related quality of life with medium cutoff dialyzers conducted in the U.S., it believed it to be the most relevant patient population but stated that no differences among groups (high flux vs. medium cutoff) were seen in any of the measures.[188]

A commenter stated that the two new publications, Blackowicz et al. and Molano et al., do not establish THERANOVA as clinically superior to other dialyzers in outcomes related to hospitalization. This commenter noted that the Blackowicz et al. analysis included causes of hospitalization that can be considered unrelated to dialysis and all occurred in the non-

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[183] 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.S 325016

[184] 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.

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

[186] 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(2):179-187. doi: 10.1159/000513328.

[187] 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 Oct;25(5):621-627. doi: 10.1111/1744-9987.13620.

[188] 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.

THERANOVA group. With the small sample size, these five hospitalizations are highly influential. However, once hospitalizations for causes unrelated to dialysis were removed, the reduction in hospitalization rate was not statistically significant between the study groups. The commenter also stated that the Molano et al. study was conducted in Columbia and may not be generalizable to the Medicare population. Additionally, the commenter noted issues with the unblinded and observational nature of the study leading to potential patient selection bias. Additional criticisms involved unbalanced patient characteristics between study groups and patients in the high flux (non-THERANOVA) group had comorbid conditions that may not have been accounted for in the weighting. The commenter agreed with CMS that patients in the THERANOVA group appeared to have more intensive dialysis at baseline with higher blood and dialysate flows compared to the high-flux group, facilitating better removal of uremic toxins overall.

The commenter submitted its own meta-analysis and stated that it found the number of studies, availability of data, and quality of available studies were not sufficient to make a conclusion on any benefit or detriment of the use of medium cutoff dialyzers in chronic HD patients. The commenter stated that with regard to the patient reported outcome data considered by the analysis, the observational studies showed varying results. The commenter also stated that studies without a comparator group may be prone to bias and thus, difficult to interpret. The commenter cited a randomized clinical trial conducted in the U.S. on medium cutoff dialyzers and stated that it found no difference in quality of life.[189]

The same commenter voiced concerns about the overall evidence in support of the applicant's substantial clinical improvement claims, noting that the CY 2023 application relies largely on the same studies as the application that was submitted for CY 2021. The commenter cited its own meta-analysis comparing hospital admissions and patient-reported outcomes,

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[189] Weiner DE, Falzon L, Skoufos L, Bernardo A, Beck W, Xiao M, Tran H. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial. Clin J Am Soc Nephrol. 2020 Sep 7;15(9):1310-1319. doi: 10.2215/CJN.01210120. Epub 2020 Aug 25. PMID: 32843372; PMCID: PMC7480550.

including quality of life, between patients dialyzed with THERANOVA versus high-flux (HF) dialyzers from published literature. The commenter stated that existing data was too weak and heterogenous to conduct such an analysis. The commenter also stated that the meta-analysis demonstrated lack of clinical benefit.

Finally, the commenter raised concerns about the use of patient survey data included in the CY2023 application, stating it did not believe weak evidentiary sources should be dispositive or substitute for high quality clinical evidence. The commenter stated that such information may be a useful supplement, but it cautioned CMS against relying on it too heavily.

Several commenters expressed concerns about albumin loss. One stated that the applicant presented no compelling information to address CMS' previously articulated concerns regarding albumin loss and its impact on patient health outcomes. One commenter cited several sources pertaining to albumin loss [190, 191, 192] and stated that these studies support the use of high-flux, as opposed to medium cutoff dialyzers, in patients with hypoalbuminemia because of higher protein removal with medium cutoff compared to high flux membranes.

Response: We appreciate the commenters' input regarding whether THERANOVA meets the TPNIES innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1).

We acknowledge the additional data supplied by the applicant regarding claims for reduced hospitalization, as well as expansion of an ongoing trial on quality of life, and the challenges associated with generating adequate sample sizes with randomized and matched cohorts. The updated studies on hospitalizations (Blackowicz et al. and Molano et al.) that have

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[190] Kalantar-Zadeh K, Ficociello LH, Bazzanella J, Mullon C, Anger MS. Slipping Through the Pores: Hypoalbuminemia
and Albumin Loss During Hemodialysis. Int J Nephrol Renovasc Dis. 2021 Jan 20;14:11-21. doi: 10.2147/IJNRD.S291348. PMID: 33505168; PMCID: PMC7829597.

[191] Zhou M, Ficociello LH, Mullon C, Mooney A, Williamson D, Anger MS. Real-World Performance of High-Flux Dialyzers in Patients With Hypoalbuminemia. ASAIO J. 2022 Jan 1;68(1):96-102. doi: 10.1097/MAT.0000000000001511. PMID: 34172639; PMCID: PMC8700293.

[192] https://www.asn-online.org/education/kidneyweek/archives/KW21Abstracts.pdf

now been published in peer reviewed journals included important details about the study design and population that were not available in the previously-submitted abstracts.

Despite this additional information, we remain concerned with potential bias in both studies. While Blackowicz et al, demonstrated a statistically significant reduction in hospitalizations among patients randomized to the THERANOVA membrane, the study was unblinded and was complicated by a high dropout rate in both the treatment and control groups. Because the choice to hospitalize patients can be subjective, the lack of blinding to the investigators introduces potential bias that weakens the quality of evidence. Some of the patients who did not complete the study might have otherwise contributed important information, such as patients who did not complete the study due to missed treatments or adverse events. The published study results focus on a marginally significant p-value that does not account for the testing of multiple outcomes. We also note that a small number of hospitalizations unrelated to dialysis have outsized statistical weight and may weaken the claim that the dialyzer plausibly reduces hospitalizations. Rather, we question whether the difference in hospitalizations may be better explained by the study design or potential spurious results due to small sample size.

The follow-on study by Molano et al. addresses some of the limitations from Blackowicz et al. Compared to the Blackowicz et al. study, this study included more patients and followed patients over a longer time period. However, patients were not randomized and there remains a possibility of bias due to imbalances between the comparison groups. For example, patients in the high flux dialyzer group had comorbidities that may not have been accounted for by the weighting. Even if the patient groups were balanced on baseline characteristics, it appears that the two groups were treated differently throughout the duration of the study, with the medium cutoff membrane group receiving more intensive dialysis. Furthermore, the results from Molano et. al. and comments reflecting clinician experience practicing outside the United States may not be generalizable to dialysis as practiced in the United States.

While the applicant responded to the issue of short-term outcomes in hospitalization by stating that statistical significance was reached at 4.5 months, suggestive of a sufficiently large magnitude of effect, we clarify that based on the evidence provided, and in the absence of a longer-term study, it is not clear whether the observed rapid reduction in hospitalizations may be better explained by bias in the study design. More specific information about the types of hospitalizations that were reduced (for example, cardiovascular, nutrition or immune related admissions) would help to address this concern by linking reductions in hospitalizations to proposed mechanisms of disease related to middle molecules. It would then be helpful to see if hospitalizations remain significantly different between the two groups after removing hospitalizations that were unlikely related to the dialyzer membrane. We also have secondary concerns about statistical significance. After correcting for multiple hypothesis testing, as is standard in high-quality clinical trials, the significance is borderline. We also agree with one commenter that some of the hospitalization differences appear to be driven by non-dialysis related hospitalizations.

As the applicant noted, inverse probability weighting can account for differences in observed features between the treatment and matched control groups. However, the approach does not correct for two additional sources of bias. First, the possibility of unobserved differences between the groups remains. The tables included in the published study do not describe the comparison groups prior to matching and do not provide the information needed to identify evidence of this potential source of bias. And second, the finding that Kt/V throughout the duration of the study was significantly different between the matched groups (higher in the medium cutoff dialyzer group) is suggestive of potential imbalances in unobserved features. Moreover, because the medium cutoff dialyzer group systematically received more intensive dialysis, we cannot deduce whether improved outcomes are attributable to the THERANOVA membrane itself or more intensive dialysis. Even an RCT where one arm systematically received more dialysis would not be able to resolve this potential bias. A comparison of the two

dialyzers, where both arms receive equivalent small-molecule clearance (i.e., equivalent Kt/V urea, which should be unaffected by the intervention) may be helpful in addressing this concern.

We also note that the Penny et al. article referenced by the applicant had several limitations including small in size, single-center, non-U.S., and lacking a control group. Future studies of patient reported outcomes could provide support by verifying that the specific domains identified in initial exploratory analyses represent areas where the new technology improves aspects of quality of life and/or pruritis and by comparing patients treated with the intervention to a control population.

With respect to the issue of multiple-hypothesis testing and non-significant differences in afternoon pruritus in Lim et al., we agree with the applicant that multiple outcomes would be a concern in any study that examines multiple quality-of-life domains. However, this does not address the specific concern. The statistics literature provides multiple strategies to correct p-values for multiple statistical tests. Additionally, as stated above, the Penny et al. article does not provide sufficient corroboration of the finding due to its own limitations. Future studies could provide reassurance by verifying that the specific domains identified in these initial exploratory analyses represent areas where the new technology improves quality of life. As the applicant notes, these studies should be robust to concerns about multiple statistical testing (given the multiple quality-of-life domains) and could attempt to minimize bias by providing comparison to an appropriate control group.

Although crossover trials have some advantages as noted by the applicant (primarily in that they use the same patient as an internal control group), we also would like to clarify that crossover trials could be designed to overcome study design flaws that may introduce bias. First, the trial should consider blinding participants and study coordinators, since an unblinded crossover trial that assesses subjective outcomes is prone to observer and recall bias. Second, because regression to the mean is common particularly with quality-of-life studies that depend on survey responses, crossover trials should consider employing randomization, where patients

are randomly assigned to the sequence of crossover intervention. Finally, we note that in the renal literature especially, high-quality crossover trials have been effectively employed to demonstrate the physiological benefits of a dialysis-related intervention.

In accordance with TPNIES policy and § 412.87(b)(1)(i), we consider 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. In addition, per 412.87(b)(1)(iii), CMS considers a range of evidence from published or unpublished information sources, including other appropriate information sources not otherwise listed under § 412.87(b)(1)(iii).

After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2023 ESRD PPS proposed rule, as well as the many comments submitted by the public, we have determined that THERANOVA has not shown that it represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. For the reasons discussed previously, we conclude that THERANOVA does not meet the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(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.[193] We welcomed comments on THERANOVA's status as a non-capital-related asset.

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[193] 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

The applicant stated that THERANOVA is not an asset that the ESRD facility has an economic interest in through ownership, and THERANOVA is not subject to depreciation. Based on the information provided by the applicant, we agree THERANOVA does not meet the definition of a capital-related asset, as defined in § 413.236(a)(2).

Final Rule Action: After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are not sufficient to demonstrate that THERANOVA meets all eligibility criteria to qualify for the TPNIES for CY 2023. As a result, THERANOVA will not be paid for using the TPNIES per § 413.236(d). We note that in the CY 2021 ESRD PPS final rule (85 FR 71412), CMS indicated that entities would have 3 years beginning on the date of FDA marketing authorization in which to submit their applications for the TPNIES. Based on the THERANOVA FDA marketing authorization date of August 28, 2020, the applicant is eligible to apply for the TPNIES for CY 2024, and CMS would review any new information provided for the CY 2024 rulemaking cycle.

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

In this section of the final rule, we provide a table that identifies the one item that was approved for the TPNIES for CY 2022[194] 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

[194] 86 FR 61889 through 61906

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,[195] dated March 15, 2022, and available at: https://www.cms.gov/files/document/r11295CP.pdf

In this section of the final 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.

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

F. Summary of 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

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

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 to add 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 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 stated 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 will 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 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 will 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.

In the CY 2023 ESRD PPS proposed rule, we presented this information and noted that price changes to the ESRD PPS 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 final rule. In addition, we noted that 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 stated that we believed 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 final rule, in the CY 2023 ESRD PPS proposed rule (87 FR 38522 through 38523), we stated that we

were 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 noted that any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance payment under the ESRD PPS. In the CY 2023 ESRD PPS proposed rule, we discussed several methods that could be used to develop an add-on payment adjustment for these drugs and biological products. As noted in the proposed rule, the methods presented below differ in terms of which formerly separately billable renal dialysis drugs and biological products will be considered for a potential add-on payment adjustment. We noted that under these potential options, we would apply a reconciliation methodology only when an add-on payment adjustment will 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, which is CY 2020 as discussed in section II.B.1.a.(1)(c) of this final 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. Summary of Request for Information on an Add-on Payment Adjustment After the TDAPA Period Ends

In the CY 2023 ESRD PPS proposed rule (87 FR 38464), we sought comment on 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 issued a request for information (RFI) to seek feedback from the public on whether an add-on payment adjustment would be needed, what the appropriate criteria would be for determining whether renal dialysis drugs or biological products should receive such an adjustment, and what methodology would be most appropriate for calculating such an adjustment.

5. Summary of Comments Received

We received 27 public comments in response to our RFI, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; and MedPAC. A high-level description of these comments is included in the following subsections of this CY 2023 ESRD PPS final rule. We will provide more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

While we will not respond to these comments in this CY 2023 ESRD PPS final rule, we intend to take them into consideration during potential future policy development. We thank the commenters for their detailed and thoughtful comments.

a. Need for Establishing an Add-On Payment Adjustment

We received 23 comments that supported CMS establishing an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends. Most commenters expressed their belief that an add-on payment adjustment of this nature is necessary to support the adoption of new renal dialysis drugs and biological products. Numerous commenters expressed support for using an add-on

payment adjustment to improve patient access to innovative drugs. MedPAC opposed this type of add-on payment adjustment by stating that it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices.

b. Criteria for Receiving Add-On Payment Adjustment

Most commenters supported CMS allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. MedPAC recommended that CMS limit the add-on payment adjustment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products reflected in the ESRD PPS bundled payment. Several commenters, including a trade association, also recommended that CMS consider applying a similar add-on payment adjustment for the equipment, supplies, and capital-related assets that are paid for under the TPNIES.

c. Calculating an Add-On Payment Adjustment

Several commenters supported reconciling the expenditure of the new renal dialysis drug or biological product with any reduction in expenditures for other formerly separately billable renal dialysis drugs that are clinically or statistically related to the introduction of the new renal dialysis drug in the bundle. Several commenters expressed their belief that the FDA-approved label for primary indication should be used to determine clinical association, rather than end-action effect. MedPAC expressed opposition to calculating any add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends, but noted that if an add-on payment adjustment were applied, it would be appropriate to use an offset, similar to the approach used with the TPNIES, to avoid duplicative payment for renal dialysis services already included in the ESRD PPS base rate.

d. Public Comments on the TDAPA and TPNIES

We received several comments regarding the TDAPA and TPNIES policies, including new payment adjustments and length of the payment period. Commenters urged CMS to apply

the TPNIES and TDAPA for at least three years to allow for two full years of data collection, and then increase the base rate to reflect the value of any improved outcomes for patients, including improved quality of life, once the TDAPA or TPNIES period ends. An LDO also suggested that the TDAPA payment amount be restored to the original ASP + 6 percent amount. Commenters also suggested that we create a pathway for incorporation of new clinical diagnostic laboratory tests related to the treatment of ESRD, either through an expansion of the TPNIES or the adoption of a parallel, Transitional Laboratory Add-on Payment Adjustment (TLAPA). We thank the commenters for their input. We did not include any proposals on these topics in the CY 2023 ESRD PPS proposed rule, and therefore we believe these comments are out of scope for this rulemaking. However, we will consider these comments for potential future refinements to ESRD PPS payment policies.

G. Summary of Requests for Information on Health Equity Issues within the ESRD PPS with a Focus on 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. CMS policy objectives, including its commitment to advancing health equity which stands as the first pillar of the CMS Strategic Plan[196] and reflect the goals of the Biden administration, as stated in Executive Order 13985.[197]

In this final 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."[198]

[196] https://www.cms.gov/cms-strategic-plan
[197] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government
[198] https://www.cms.gov/pillar/health-equity

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 patients with higher levels of income.[199,200,201,202,203,204] When compared to FFS beneficiaries not receiving renal dialysis services, FFS beneficiaries receiving renal dialysis are disproportionately young, male, Black/African-American, low income as measured by dually eligible Medicare and Medicaid status, have disabilities, and reside in an urban setting[205] In the CY 2023 ESRD PPS proposed rule (87 FR 38464), we requested information on advancing health equity under the ESRD PPS, including an additional request focused on health disparities faced by pediatric ESRD patients within the ESRD PPS (87 FR 38523 through 38529).

2. Summary of Requests for Information on Health Equity Issues within the ESRD PPS

We received comments on these issues from approximately 13 commenters that directly and indirectly addressed these RFI topics. Below we provide a short synopsis of the comments for each of the RFI topics discussed in the CY 2023 ESRD PPS proposed rule. We will provide a more detailed summary of the comments received on this RFI on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ESRDpayment/Educational_Resources.html. While we will not respond to

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[199] 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.

[200] 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

[201] 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.

[202] 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.

[203] 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

[204] 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.

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

these comments here, we will take them into consideration during future policy development. We thank the commenters for their detailed and thoughtful comments.

a. Refinements to Mitigate Health Disparities

CMS requested information on what kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity. In response, many commenters expressed support for CMS's efforts to reduce disparities and improve equity in the delivery of ESRD care. One commenter noted that traditional incentives for health care providers and payers to deliver high quality care efficiently may require change so that incentives are applied fairly and do not undermine access to care. Commenters offered a number of suggestions, including: add-on payments and other adjustments to the facility payor mix to provide for social work staffing and complex care coordination; add-on payments for higher percentages of dual eligible home dialysis patients and patients with housing or food insecurities; and an extension of kidney disease patient education services benefits to Medicare beneficiaries are who not yet on dialysis but who have Stage V CKD as well as to those within the first 6 months of ESRD. A few commenters supported adoption of a payment model similar to the CMS's ESRD Treatment Choices (ETC) Model to improve health equity; one commenter advocated for allowing facility-employed social workers, dieticians, and others to work with physicians to provide KDE services to beneficiaries. One commenter suggested that CMS expand equitable access to life-saving dialysis care by issuing guidance to all states to encourage expansion of Emergency Medicaid to undocumented people with kidney failure.

b. Comorbidities

CMS asked whether specific comorbidities should be examined when calculating the case-mix adjustment that would better represent the ESRD population and help address health disparities. Several commenters provided feedback on the role of comorbidities on the health outcomes of ESRD patients and recommendations around the use of comorbidities in the

ESRD PPS. Several commenters opined that the current comorbidity case mix adjusters are methodologically unsound and should be eliminated from the ESRD PPS. One commenter explained that its analysis showed effects of comorbidities on resource utilization for separately billable items, independent of the onset of dialysis, and noted that costs are higher for patients with comorbidities during the first 4 months of treatment. One commenter suggested development of patient-level adjusters to account for patients with left ventricular assist device, tracheostomy, cardiomyopathy with ejection fraction at or under 20, significant mental health conditions, non-weight bearing transfers, and patients who chose to skip >50 percent of treatments in a given month. A few commenters remarked upon the role of mental health and neurological conditions (for example, cognitive impairment), noting that such conditions affect patients' ability to function and adhere to care regimens. Two commenters referenced research produced by MedPAC and The Moran Company as resources to inform CMS policy on comorbidities and claims adjustment.

c. Subpopulations

CMS requested comment about specific subpopulations whose needs may not adequately accounted for by the current ESRD PPS payment policy and should be evaluated for potential health disparities. Several commenters remarked upon the large percentage of ESRD patients who are dual eligible and who have higher costs of care despite similar utilization. Several commenters supported the inclusion of social determinants of health (SDOH) measures identified by CMS in the CY 2023 ESRD PPS proposed rule as health-related social needs (HRSN): food insecurity, housing instability, transportation problems, utility help needs, interpersonal safety, mental health needs, and non-English speaking. Other commenters spoke to the lack of caregiver support, the burden of caregiver fatigue, and concerns about storage and supplies management as factors contributing to health disparities, including the lack of access to home dialysis. Another commenter noted the lack of health

literacy as a contributing factor to disparities. One commenter cited the lack of high-speed internet as a contributor to disparities in telehealth access and thus in access to home dialysis.

CMS also asked how existing data sources could be used to better identify unmet needs among specific subpopulations that could result in health disparities. In response, one commenter noted that mental health conditions are coded using ICD-10 codes and should be available in claims data. The same commenter also suggested that CMS develop and use Z codes to track SDOH, but, until these were operational, CMS might instead use dual eligible status or Area Deprivation Index (ADI) and Social Vulnerability Index (SVI) at the 9-digit ZIP code level. The commenter noted that frequent address changes in CMS claims for a given patient might indicate housing instability. One commenter recommended screening for CKD using the CMS-2728 patient registration form.

d. Demographic Information and Social Determinants of Health

CMS asked for comments suggesting ways to address, define, collect, and use accurate and standardized, self-identified demographic information (including information on race and 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 mitigate disparities and refine ESRD PPS payment policy. In response, commenters indicated support for collecting SDOH, but also cautioned against the accompanying increased administrative burden on staff. A provider advocacy organization suggested working with facilities already tracking SDOH through electronic medical records and then engaging vendors to extract the data. A large dialysis organization advocated for a voluntary pilot study to (1) support the uniform collection and analysis of patient-level SDOH data and (2) test interventions. A few commenters suggested the use of Z codes to collect data on common SDOH such as housing and food insecurity and minimal caregiver support. One commenter advocated for CMS's use of the HRSN screening tool and mental health variables to identify subgroups in need; the commenter also suggested looking

to past studies on HRSNs from the early 1980s and how these were used to develop DRGs for data on empirical estimates of the additional costs from HRSNs. One commenter noted its own success with SDOH collection and suggested that CMS look to the standardized data collection methods described in the 2009 Institute of Medicine reporting on standardized collection of race, ethnicity, and language data.

e. Revisions to Case-mix Categories in the ESRD PPS

CMS sought comment on what revisions to case-mix categories in the ESRD PPS could be made to better represent underserved populations. One commenter recommended that CMS adopt a payment adjustment for ESRD facilities treating a large proportion of patients with SDOH challenges that would be similar to the Disproportionate Share Hospital (DSH) payment available to hospitals under the IPPS. One commenter suggested CMS use the Complication or Comorbidity (CC) or a Major Complication or Comorbidity (MCC) approach, as used in IPPS. That is, the existing categories could be modified to include two or three levels of HRSNs as modifiers, with higher levels of HRSNs being associated with higher payments. The commenter noted that this approach would leave the basic case-mix system unchanged but would add a HRSN concept exactly analogous to the CC modifier – an additional, orthogonal factor that contributes to cost and can contribute to payment.

f. Renal Dialysis Technologies, Treatments, and Clinical Tools

CMS asked for comment regarding what 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. One commenter suggested that CMS work with the HHS Office for Civil Rights to address health literacy issues and improve education materials. Another commenter suggested that CMS incorporate the use of peer mentors and navigators to assist in education of ESRD patients as well as to help with minority recruitment into primary care settings and nephrology training. Similarly, one commenter suggested that CMS incentivize medical students to pursue nephrology. A

non-profit dialysis center discouraged CMS from over-adjusting for SDOH in a way that would move the payment system away from bundled payments and towards an FFS approach and accordingly in their view undermine the ESRD PPS.

3. Responses to the Request for Information on Health Equity Issues within the ESRD PPS Focusing on Pediatric Payment

a. Pediatric Dialysis Overview[206]

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. Pediatric facilities have higher direct patient care labor expenditures than adult facilities. 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. Some organizations emphasized 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 of these 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, some panelists provided suggestions for the pediatric dialysis payment adjustment.[207]

b. Summary of Comments

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. In the CY 2023 ESRD PPS proposed rule, we requested comments on improving CMS's ability to detect and reduce health disparities

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[206] 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

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

within the ESRD PPS for pediatric patients receiving renal dialysis services. Our goal in publishing the RFI in the CY 2023 ESRD PPS proposed rule was to solicit input on topics such as circumstances and health inequities unique to the pediatric dialysis population, possible refinements to the ESRD PPS payment policy to mitigate health disparities for this population, the possible inclusion of a specific payment modifier on the claim indicating pediatric dialysis, and putting more emphasis on pediatric comorbidities.

We received comments on these issues from approximately 10 commenters that directly and indirectly addressed the RFI topics stated in the previous paragraph. Below we provide a short synopsis of the comments for each of the topics discussed in the CY 2023 ESRD PPS proposed rule. We will provide a more detailed summary of the comments received on this RFI on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ESRDpayment/Educational_Resources.html.

Some commenters stated that they appreciated that CMS acknowledges the unique and complex care needs of the pediatric dialysis patient population that typically requires a much higher intensity of labor-related services and additional supplies. These unique and complex care needs contribute to the higher cost of pediatric ESRD and CKD care. Some commenters thanked CMS for our continued engagement with them regarding this specialized population.

All commenters stated that they agree there are health disparities faced by pediatric patients receiving dialysis that are different than adults receiving dialysis. Some commenters reiterated the health disparities faced by Black pediatric dialysis patients, noting that Black pediatric patients are disproportionally impacted by CKD overall. Some commenters pointed to data showing Black children receiving dialysis are more likely to be on hemodialysis than White patients and wait longer, and are less likely, to receive a kidney transplant. These differences are significant because home dialysis, and ultimately transplant, are the preferred treatments for ESRD in the pediatric population. While outside the scope of the RFI, a few commenters expressed concern with the algorithms, including race as a factor, used to match

kidneys of deceased donors to pediatric kidney transplant recipients, noting it may negatively impact overall access to transplantation for children. Commenters also pointed to socioeconomic and demographic factors that contribute to the disparity of Black children receiving transplants.

c. Factors Affecting the Cost of Pediatric Dialysis Treatment and the Need for Data Collection

Almost all the commenters discussed economic determinants of health and SDOH. They pointed to factors such as lack of adequate housing, nutrition, and transportation as problems these children face that contribute to the disparity for this sub-population. Housing insecurity was one of the SDOH discussed in the comments. Nutritional concerns were another topic of discussion by several commenters. Some commenters highlighted the need to address food insecurity and access to nutritional foods to address disparities and advance health equity. SDOH are not currently collected as part in the ESRD PPS case mix adjustment model, but commenters noted their value in accessing the care needs of the pediatric dialysis population.

In addition to discussing SDOH, interested parties expressed concern that there is other information not currently collected that affects the true costs of pediatric dialysis treatment within the ESRD PPS. For example, they stated that other existing medical conditions are not factored into case-mix adjustment for pediatric patients, nor are the costs associated with the type of specialized treatment required by the youngest patients and those with developmental and other disabilities and special needs. All the commenters suggested factors to consider for the pediatric patient level case-mix adjuster. Commenters requested CMS consider the additional unreported expenses for the key support personnel responsible for addressing the unique challenges related to cognitive, physical, and developmental disabilities in these patients.

In the CY 2023 ESRD PPS proposed rule (87 FR 38464), CMS asked whether a pediatric dialysis payment should include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options. Some commenters supported the inclusion of a modifier; others supported the formation of a separate pediatric ESRD PPS.

Response: We appreciate all the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our ESRD payment policy as we work to address health disparities in the pediatric dialysis population. We will continue to take the comments into account as we work on improving CMS's ability to detect and reduce health disparities within the ESRD PPS for pediatric patients receiving renal dialysis services. 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. 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 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. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2023 Payment for Renal Dialysis Services Furnished to Individuals with AKI

The proposed rule, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (87 FR 38464 through 38586), referred to as the "CY 2023 ESRD PPS proposed rule," appeared in the June 28, 2022 version of the **Federal Register**, with a comment period that ended on August 22, 2022. In that proposed rule, we proposed to update the AKI dialysis payment rate for CY 2023. We received 13 public comments on our proposal from a coalition of dialysis organizations, a non-profit dialysis association, a device manufacturer, a network of dialysis organizations and regional offices, a home dialysis advocacy organization, a home dialysis stakeholder alliance, a professional association, a professional organization of nephrologists, two trade associations, a national

organization of patients and kidney healthcare professionals, a coalition of healthcare organizations, and a large dialysis organization.

In this final rule, we provide a summary of each proposed provision, a summary of public comments received and our responses to them, and the policies we are finalizing for CY 2023 payment for renal dialysis services furnished to individuals with AKI.

C. 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 final rule, the CY 2023 ESRD PPS base rate is $265.57, which reflects the application of the CY 2023 wage index budget-neutrality adjustment factor of 0.999730 and the CY 2023 ESRDB market basket increase of 3.1 percent reduced by the productivity adjustment of 0.1 percentage point, that is, 3.0 percent. Accordingly, we are finalizing a CY 2023 per treatment payment rate of $265.57 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 final 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 ESRDB 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 final 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 finalizing a CY 2023 AKI dialysis payment rate of $265.57, adjusted by the ESRD facility's wage index. The wage index floor increase (discussed in section II.B.1.b.(3) of this final rule) and the permanent 5-percent cap on wage index decreases (discussed in section II.B.1.b.(2) of this final rule) that we are finalizing the ESRD PPS will apply in the same way to AKI dialysis payments to ESRD facilities.

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

Comment: Many commenters, including two trade associations, a national organization of patients and kidney healthcare professionals, a coalition of healthcare organizations, a home dialysis stakeholder alliance, a non-profit dialysis association, and a large dialysis organization, requested that CMS change Medicare AKI policies to include at-home hemodialysis and peritoneal dialysis for AKI beneficiaries. Some commenters also sought to have the ESRD PPS cover staff-assisted dialysis at home, patient education, and home training sessions. A few commenters advocated for home dialysis waivers that would extend to outpatient AKI dialysis under the current PHE for COVID-19. Several commenters reported that they were finding home dialysis to be a safe and effective modality, as many patients with AKI have received home dialysis under a waiver applicable to acute hospital care delivered at home under CMS' Hospitals Without Walls program. Many commenters also advocated for the home dialysis modality, arguing that home dialysis options for AKI patients would advance health equity, noting that Black people are more likely than White people to experience AKI.

Response: We thank the commenters for their input. We did not include any proposals on these topics in the CY 2023 ESRD PPS proposed rule, and therefore we believe these comments are out of scope for this rulemaking. However, we will consider these comments for future refinements to AKI payment policies. We note that currently CMS will only pay for renal dialysis services at an ESRD facility for patients with AKI, and we did not propose to change this policy in the CY 2023 ESRD proposed rule. Current AKI dialysis payment policy was implemented under the CY 2017 ESRD PPS final rule (81 FR 77866 through 77872, and 77965). Over the years, we have received several comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI. We have solicited comments in the recent past, including in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408), when we requested information regarding potentially modifying the site of renal dialysis services for patients with AKI and payment for AKI in the home setting. CMS continues to believe that this population requires close medical supervision by qualified staff during their dialysis treatment.

Comment: A few commenters, including a coalition of dialysis organizations and a large dialysis organization, urged CMS to share information about any specific data elements and monitoring plans, as well as the data it is collecting and analyzing while monitoring the AKI benefit.

Response: We appreciate the commenters' support for continued claims data monitoring and analysis. These issues were not the subject of proposals for CY 2023 and therefore are out of scope for this rulemaking. However, we note that we have been monitoring the trends of AKI beneficiaries in ESRD facilities and acute inpatient hemodialysis. This has included quantification of drugs, laboratory tests and other services provided on acute inpatient dialysis claims. We also examine other diagnoses recorded before an acute inpatient dialysis claim. We continue to analyze costs, utilization, patient characteristics, sites of service, as well as data for COVID-19 patients who have experienced AKI. The results of the data analysis will be shared in the future in public use files on the ESRD PPS website and we plan to engage with interested

parties further on this issue.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2023 ESRD PPS base rate is $265.57. Accordingly, we are finalizing a CY 2023 per treatment payment rate of $265.57 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

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 will 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 will 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 will 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 did not propose any changes to the measure suppression policy.

2. Suppression of Seven 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.[208] Provisional life expectancy data for CY 2020 showed that COVID-19 reduced life expectancy by 1.5 years

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

overall, with the estimated impact disproportionately affecting minority communities.[209] 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.[210] With a death toll surpassing that of the 1918 influenza pandemic, COVID-19 is the deadliest disease in American history.[211]

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.[212] Further, in November 2021, the number of COVID-19 deaths for 2021 surpassed the total deaths for 2020. According to Centers 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.[213] 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 (86 FR 61913 through 61917), 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

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[209] 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.
[210] 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.
[211] 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/.
[212] 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.
[213] https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.

- 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, in the CY 2023 ESRD PPS proposed rule (87 FR 38531 through 38538), we proposed 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 be significantly better or significantly worse compared to historical performance during the immediately preceding program years).

Although we had previously finalized that the mTPS for PY 2023 would be 57, as well as an associated payment reduction scale (85 FR 71471), we proposed in the CY 2023 ESRD PPS proposed rule to update the mTPS and payment reduction scale to reflect our proposal to suppress six measures for PY 2023, which together constitute nearly half of the ESRD QIP measure set (87 FR 38532). We also proposed to amend 42 CFR 413.178(a)(8) to state that the definition of the mTPS does not apply to PY 2023. The measures that we proposed to score for PY 2023 were 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. In the CY 2023 ESRD PPS proposed rule, we stated that the proposed re-calculated mTPS for PY 2023 will be 80. We also stated that if one or more of our measure suppression proposals is not finalized, then we would revise the mTPS for PY 2023 so that it includes all measures that we

finalize for scoring for PY 2023 (87 FR 38532). We also proposed to codify these proposals in our regulations by adding a new 42 CFR § 413.178(i), which will specify 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. We stated that 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). We note that § 413.178(i) is updated in this final rule to reflect our additional suppression of the Standardized Fistula Rate clinical measure for PY 2023, which we discuss in IV.B.2.d of this final rule. As discussed in section IV.C of this final rule, we are also finalizing our proposal to calculate the performance standards for PY 2023 using CY 2019 data, and we are finalizing our proposal to revise our regulations at § 413.178(d)(2) to reflect this finalized policy.

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 health care quality in the dialysis facility setting.[214]

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, health care providers have gained experience managing the

[214] 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

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,[215] 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.[216, 217] 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.[218, 219] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits[220], N-95 masks[221], and increase COVID-19 testing in schools[222], 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 will 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 will then calculate a TPS for each eligible facility and use the established methodology to determine whether the facility will receive a payment

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[215] 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

[216] 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/.

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

[218] 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

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[220] 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/

[221] 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

[222] 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/

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.

We received public comments on our measure suppression proposals, and we respond to them below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023. Several commenters expressed support for the proposed measure suppressions because national performance has been distorted due to the impact of the PHE. One commenter noted that the substantial impact of the PHE on ESRD patients due to increased risk of infection, reinfection, and complications from COVID-19 is also underscored by the workforce shortage.

Response: We thank commenters for their support.

Comment: A few commenters supported the policy to publicly report suppressed measure data and PY 2023 performance scores with appropriate caveats.

Response: We thank commenters for their support.

Comment: Several commenters recommended that CMS suppress all measures for PY 2023. A few commenters requested that CMS suppress all ESRD QIP measures for PY 2023 due to current economic conditions, workforce shortages, and continued challenges stemming from the impact of the COVID-19 PHE on facilities. One commenter suggested that remaining ESRD QIP measures could be suppressed under Measure Suppression Factor 4 due to severe staffing and supply shortages that impacted facilities in CY 2021.

Response: We thank the commenters for their recommendation and acknowledge commenters' concerns regarding economic conditions, workforce shortages, and continued challenges due to the COVID-19 PHE. However, we disagree with these commenters that measure suppression is necessary for all ESRD QIP measures for PY 2023 because our analyses do not indicate that all ESRD QIP measures are eligible for suppression under our previously

finalized Measure Suppression Factors. Following publication of the CY 2023 ESRD PPS proposed rule, we considered public comments and updated our analyses to determine whether measure suppression continued to be appropriate for the measures we proposed to suppress, and also whether measure suppression was warranted for any of the measures we did not propose to suppress in the proposed rule. With the exception of the Standardized Fistula Rate clinical measure, which we are finalizing for suppression as discussed in section IV.B.2.d of this final rule, we concluded that the remaining non-suppressed measures have not been affected by the COVID-19 PHE such that measure suppression would be warranted under our previously finalized Measure Suppression Factors. For example, our analyses of measure score distributions for non-suppressed measures for PY 2023 indicate that they are generally consistent with historical measure score distributions for those measures. Therefore, we concluded that non-suppressed measures did not experience significant deviation in national performance during the COVID-19 PHE in PY 2023 and would not be eligible for measure suppression under Measure Suppression Factor 1. Nothing in our analyses indicated that these measures would be eligible for measure suppression under Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE, or 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. Although Measure Suppression Factor 4 permits measure suppression where there have been significant national shortages or rapid or unprecedented changes in healthcare personnel, such as in the ICH CAHPS measure and the PPPW clinical measure (as discussed in IV.B.2.e and IV.B.2.f of this final rule), our analyses did not indicate that the remaining measures were significantly impacted due to such changes. We note that general changes in economic conditions are not justifications for measure suppression under our previously finalized measure

suppression policy. Although we appreciate the continuing impact of the COVID-19 PHE on facilities in CY 2021, we believe that facilities have had time to adjust to the new COVID-19 health care landscape and should be scored on those measures which our analyses have indicated were not significantly impacted by the COVID-19 PHE in CY 2021. We disagree with the commenter's suggestion that all remaining ESRD QIP measures could be suppressed due to severe staffing and supply shortages in CY 2021. Although we are aware of anecdotal reports indicating the impact of staffing and supply shortages on facilities, our analyses did not support measure suppression under Measure Suppression Factor 4 for non-suppressed measures.

Comment: One commenter recommended that CMS suppress the NHSN BSI clinical measure under Measure Suppression Factor 3 due to changes in clinical guidelines and care delivery in response to the COVID-19 PHE. The commenter noted that the COVID-19 PHE has created challenges in care delivery and treatment related to catheter removal and fistula insertion, which has led to the use of more catheters and increased likelihood of infection.

Response: Suppressing the NHSN BSI clinical measure would not be appropriate under Measure Suppression Factor 3 based on our analyses. To be eligible for measure suppression under Measure Suppression Factor 3, there must be 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. Our analyses did not indicate the existence of such an impact on the number of new positive blood culture events based on blood cultures drawn as an outpatient or within one calendar day after a hospital admission, nor is such impact reflected in measure score distributions for the NHSN BSI clinical measure for PY 2023. Although challenges in care delivery and treatment related to catheter removal and arteriovenous fistula (AVF) creation may have resulted in an increased likelihood of patient infection in certain cases, our analyses did not

indicate that either of those circumstances directly resulted in patients developing more bloodstream infections due to the COVID-19 PHE.

Comment: One commenter recommended that CMS suppress the Ultrafiltration Rate reporting measure, noting that the Ultrafiltration Rate measure requires input of a Kt/V date and the Kt/V Dialysis Adequacy measure is proposed for suppression for PY 2023. The commenter expressed concern that this will impact a provider's ability to report the Ultrafiltration Rate measure and therefore the Ultrafiltration Rate reporting measure should also be suppressed.

Response: We disagree that it is necessary to suppress the Ultrafiltration Rate reporting measure because the measure specifications include data that are also used to calculate the Kt/V Dialysis Adequacy clinical measure. Although we proposed (and are finalizing below) that we would suppress the Kt/V Dialysis Adequacy measure for PY 2023 for use in scoring, facilities will still be required to report data on that measure (as well as on all other PY 2023 suppressed measures), including the Kt/V date. Therefore, the suppression of the Kt/V Dialysis Adequacy clinical measure should not impact a facility's ability to complete the data submission requirements for the Ultrafiltration Rate reporting measure.

Comment: One commenter recommended that CMS also suppress the Hypercalcemia clinical measure for PY 2023, stating that it does not make sense to score the measure in light of CMS's proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning with PY 2025. The commenter also stated that the Hypercalcemia measure should be suppressed under Measure Suppression Factor 4 due to shortages in prescription drugs needed to treat hypercalcemia.

Response: We disagree with the commenter's suggestion that we should suppress the Hypercalcemia clinical measure in PY 2023 because we proposed to convert that measure to a reporting measure beginning with PY 2025. Whether a measure is a clinical measure or a reporting measure is irrelevant to whether suppression is warranted under our previously finalized measure suppression policy, which enables us to suppress the use of measure data for

scoring and payment purposes if we determine that circumstances caused by the COVID-19 PHE have affected a given measure. Our analyses indicate that facility performance on the Hypercalcemia clinical measure was not significantly impacted by the COVID-19 PHE in CY 2021 for PY 2023, as the scoring simulations for the Hypercalcemia clinical measure showed that measure performance was consistent with performance from previous years. Therefore, the measure would not be eligible for measure suppression under Measure Suppression Factor 1. We did not observe any data for CY 2021 indicating a proximate relationship between bone mineral metabolism to the health impacts of the COVID-19 PHE. Therefore, the measure would not be eligible for measure suppression under Measure Suppression Factor 2. To be eligible for measure suppression under Measure Suppression Factor 3, there must be 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. Our data showed that measure performance remained high and did not indicate the existence of such an impact on the number of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing, nor is such impact reflected in measure score distributions for the Hypercalcemia clinical measure for PY 2023. Finally, we did not observe that the measure was affected by significant national shortages or rapid or unprecedented changes in patient-case volumes or facility-level case mix to be eligible for suppression under Measure Suppression Factor 4. Therefore, we concluded that suppression of the Hypercalcemia clinical measure is not warranted under any of our previously finalized Measure Suppression Factors.

Comment: Many commenters recommended that, in addition to measure suppression, CMS suspend scoring and payment penalties for PY 2023 similar to the special scoring and payment policy for PY 2022. Several commenters recommended that CMS avoid enforcing penalties for the PY 2023 ESRD QIP due to continued challenges faced by facilities during the

COVID-19 PHE, such as current economic conditions, workforce shortages, patient reluctance to seek care for fear of COVID-19 infection, and increased rates of kidney failure because of COVID-19. A few commenters expressed concern that the PHE has impacted facilities' ability to report data and that the decreased data submissions will skew data results. One commenter also cited data integrity issues in EQRS as a reason for suspending penalties in PY 2023. A few commenters suggested that suspending scoring and penalties for PY 2023 will align with the approach taken by the Hospital Value-Based Purchasing (VBP) Program, stating that the scoring methodology will not accurately reflect facility performance during the COVID-19 PHE.

Response: We thank the commenters for their suggestions, but we disagree that a special scoring and payment policy for PY 2023 is necessary. Although we finalized a special scoring and payment rule for PY 2022 in the CY 2022 ESRD PPS final rule, we note that the circumstances surrounding that policy were quite different. First, the PY 2022 performance period was shortened by an ECE granted by CMS during the beginning of the COVID-19 PHE, which allowed dialysis facilities to focus on pandemic response instead of reporting quality measure data for the first and second quarter CY 2020 data. Second, in light of data submission issues associated with the transition to EQRS, we were concerned about the amount of reliable CY 2020 data that would be available for scoring. In CY 2021 for PY 2023, although some of the measures are still impacted by the PHE, we believe that facilities have had time to begin adjusting to the new COVID-19 health care landscape and should be scored on those measures which our analyses have indicated were not significantly impacted by the PHE. Our analyses indicate that data submissions for non-suppressed measures have not decreased so significantly such that they will skew data results, and that we have resolved any issues with EQRS that could impact the integrity of the data for PY 2023 and for subsequent years going forward. Regarding the comments recommending that we suspend scoring and payment to align with other VBP programs, we note that although certain VBP programs included special scoring and payment rules for FY 2023 in the FY 2023 IPPS/LTCH PPS final rule, we believe the circumstances are

different for the ESRD QIP. In the CY 2023 ESRD PPS proposed rule, we proposed to suppress less than half of the total measures in the ESRD QIP measure set for PY 2023 and facilities will still be eligible to be scored on measures in three out of the four total domains (87 FR 38531 through 38538). By contrast, the Hospital VBP Program suppressed more than half of the measures in its program and hospitals would only be eligible to be scored on measures in two out of the four total domains (87 FR 49094 through 49105). Although we are now suppressing half of the current ESRD QIP measures with the additional suppression of the Standardized Fistula Rate measure, which we discuss in section IV.B.2.d of this final rule, facilities will still be eligible to be scored on measures in three out of the four total domains.

Comment: Several commenters expressed concern that scoring facilities on non-suppressed measures will not produce a meaningful representation of a facility's quality performance due to a skewed TPS, resulting in unfair penalties for facilities. A few commenters expressed concern on the proposal to recalculate the mTPS for non-suppressed measures for PY 2023. One commenter noted that 80 is a very high mTPS especially in light of the ongoing pandemic and that resulting PY 2023 penalties for clinics may be higher than they would otherwise be with a full measure set. A few commenters noted that the impact of the suppressed measures on the mTPS would skew the scoring of non-suppressed measures by significantly shifting the weight of measures such as the Clinical Depression reporting measure, the Standardized Fistula Rate measure, and the STrR reporting measure. One commenter also expressed concern with the resulting increased weights of the Hypercalcemia measure and the NHSN BSI clinical measure in scores for PY 2023.

Response: Although we acknowledge these commenters' concerns, we believe that it is appropriate to score facilities on non-suppressed measures. We are not suppressing these particular measures because our analyses have indicated that they were not significantly impacted by the COVID-19 PHE to fit within the scope of our measure suppression policy, as applied to PY 2023. Scoring a facility on non-suppressed measures will provide meaningful

information to patients and caregivers regarding that facility's performance on those non-suppressed measures. Therefore, we believe that it is appropriate to finalize our proposal to update the mTPS for PY 2023 so that it only includes non-suppressed measures. We note that, with the additional suppression of the Standardized Fistula Rate clinical measure as discussed in section IV.B.2.d of this final rule, the recalculated mTPS for PY 2023 will be 83. We provide the updated payment reduction scale for PY 2023 in Table 16 below:

TABLE 16: Finalized Payment Reduction Scale for PY 2023 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-83	0%
82-73	0.5%
72-63	1.0%
62-53	1.5%
52-0	2.0%

Although the recalculated mTPS for PY 2023 is higher than we proposed in the proposed rule, we estimate that fewer facilities will receive payment reductions for PY 2023. We anticipate that only approximately 10.5 percent of facilities will receive payment reductions for PY 2023 with the recalculated mTPS of 83. For comparison, in the CY 2021 ESRD PPS final rule, we estimated that approximately 24.2 percent of facilities would receive payment reductions for PY 2023 based on our previously finalized mTPS of 57 (85 FR 71480). Although we acknowledge that certain measures may be weighted more heavily due to the reduced measure set, we do not believe this will result in facilities being unfairly penalized for their performance on those measures because our analyses indicate that facility performance on those measures remains high.

Comment: One commenter expressed support for CMS's intention to resume the use of all measure data for the PY 2024 ESRD QIP, and noted its appreciation for CMS's flexibilities in response to the PHE thus far.

Response: We thank the commenter for its support.

Final Rule Action: After considering public comments, we are finalizing our proposal to amend 42 CFR 413.178(a)(8) to state that the definition of the mTPS does not apply to PY 2023. Additionally, we are finalizing the addition of a new § 413.178(i). The version of § 413.178(i) that we are finalizing is different than the proposed § 413.178(i) due to our additional suppression of the Standardized Fistula Rate clinical measure for PY 2023, which we discuss in IV.B.2.d of this final rule. Section 413.178(i) will specify that we will calculate a measure rate for each of the suppressed measures listed in § 413.178(i)(1), but will not score facility performance on those suppressed measures or include them in the facility's TPS for PY 2023. Section 413.178(i) will also specify that we will score facility performance on each of the non-suppressed measures listed in § 413.178(i)(2).

b. Suppression of the SHR Clinical Measure for PY 2023

In the proposed rule, we proposed to suppress the SHR 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 as compared to historical performance during the immediately preceding program years (87 FR 38532 through 38533). We referred 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 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 will 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.

In the CY 2023 ESRD PPS proposed rule, we stated that 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 (87 FR 38533). 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 stated our belief 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 stated that we continue to be concerned about the effects of the observed COVID-19 hospitalizations on the SHR clinical measure. We also noted 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.[223,224] Because of the increased hospitalization risk associated with COVID-19 and the Medicare dialysis patient population, we stated our concern that these

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[223] 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

[224] 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

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[225] and mortality rates[226] were 6 times higher in the ESRD population. Although our initial measure suppression analysis focused on CY 2020 and CY 2021 data and we only had partial CY 2021 data available at the time of the proposed rule, our updated analyses indicate that the remaining 2021 data continued 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 December 2021.

Following emergence of the Delta variant in 2021, we noted that 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 stated that we were 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 stated our belief 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 believed 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.

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[225] https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-services-through-2021-08-21.pdf.
[226] 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.

In the proposed rule, we stated our belief that the SHR clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the COVID-19 PHE will continue affecting measure performance on the current SHR clinical measure such that we will not be able to score facilities fairly or equitably on it for PY 2023. We proposed 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 proposed 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 noted our intent 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 discussed 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 the CY 2023 ESRD PPS proposed rule (87 FR 38538).

We welcomed public comment on our proposal to suppress the SHR clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the SHR clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID-19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in SHR clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID-19 PHE on national performance and justifies suppression of the SHR clinical measure under Measure Suppression Factor 1.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SHR clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

c. Suppression of the SRR Clinical Measure for PY 2023

In the proposed rule, we proposed 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 (87 FR 38533 through 38534). We referred 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 will 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.

In the proposed rule, we stated that based on our analysis, we have found that index discharge hospitalizations involving dialysis patients diagnosed 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 noted 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. We stated that although our measure suppression focuses on CY 2021 data and we only have partial CY 2021 data available at this time, we believed 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 noted that we were still analyzing the data for 2021, we believed that similar to 2020, these competing outcomes of index hospitalization continued 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 remained concerned about the effects of these observations on the calculations for the SRR clinical measure. We noted 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 stated our belief 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 believed 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. Since the proposed rule, our updated analyses found that COVID-19 infection continued to impact the SRR clinical measure throughout CY 2021.

In the proposed rule, we stated our belief that the SRR clinical measure is an important part of the ESRD QIP Program measure set. However, we remained concerned that the PHE for the COVID-19 pandemic continued 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 proposed 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 noted our intent 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 discussed 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 the CY 2023 ESRD PPS proposed rule (87 FR 38538).

We welcomed public comment on our proposal to suppress the SRR clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the SRR clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID-19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in SRR clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID-19 PHE on national performance and justifies suppression of the SRR clinical measure under Measure Suppression Factor 1.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SRR clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

d. Suppression of the Long-Term Catheter Rate Clinical Measure for PY 2023

In the proposed rule, we proposed 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 (87 FR 38534 through 38535). We referred 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.

In the CY 2023 ESRD PPS proposed rule, we stated that our analysis based on the available data indicated that long-term catheter use rates increased significantly during the COVID-19 PHE (87 FR 38534). 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). In the CY 2023 ESRD PPS proposed rule, we noted that 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 (87 FR 38534). By contrast, the unadjusted catheter rates in CY 2019 peaked at 12 percent. We stated our belief 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 were concerned that the COVID-19 PHE continued 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 health care facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID-19 precautions at health care 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 stated our belief that the Long-Term Catheter Rate clinical measure is an important part of the ESRD QIP measure set. However, we were 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, we stated that 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 noted that 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 stated our intent to publicly report PY 2023 data where feasible and appropriately caveated.

We welcomed public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the Long-Term Catheter Rate clinical

measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID-19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in Long-Term Catheter Rate clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID-19 PHE on national performance and justifies suppression of the Long-Term Catheter Rate clinical measure under Measure Suppression Factor 1.

Comment: Several commenters recommended that CMS also suppress the Standardized Fistula Rate measure, expressing concern that performance on the Standardized Fistula Rate measure is directly linked to the Long-Term Catheter Rate measure that was proposed for suppression and noting that the same factors impacting the Long-Term Catheter Rate measure also impacted the Standardized Fistula Rate measure because the COVID-19 PHE impacted patient access to vascular access related procedures. A few commenters noted that vascular access procedures were halted and slowed due to the PHE, which meant that patients were not able to access fistula-related procedures or treatment, leading to an increase in long-term catheter use and a decrease in the placement of fistulas. A few commenters requested that CMS suppress the Standardized Fistula Rate measure under Measure Suppression Factor 1 because the measure experienced a significant deviation in national performance during the pandemic. One commenter recommended that CMS suppress the Standardized Fistula Rate measure under Measure Suppression Factor 4, due to shortages in healthcare personnel. The commenter stated that due to the personnel shortage, facilities have had challenges finding available vascular surgeons for fistula placements.

Response: We thank commenters for their feedback. Although we initially considered proposing suppression of the Standardized Fistula Rate measure, we concluded at the time we developed the proposed rule that the measure should not be suppressed under any of the Measure

Suppression Factors based on the data available at that time. However, since the proposed rule, we have updated our analyses and have reviewed newly available updated measure data that captures national fistula rates over the entirety of CY 2021. Based on these updated data, as described in Tables 17, 18, and 19 below, we have concluded that the Standardized Fistula Rate clinical measure should be suppressed PY 2023 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. Table 17 shows that we have found significant (p-value <0.001) deviation in national fistula rates in CY 2021 compared to CY 2019. Table 18 shows the significant decline in national fistula rates over the course of CY 2021, which we believe aligns with COVID-19 surges throughout that year. Finally, Table 19 shows the relationship between long-term catheter rates and standardized fistula rates during CY 2021 – that is, as catheter rates increased, fistula rates correspondingly decreased. We believe these updated analyses, which now capture national fistula rates for all of CY 2021, support the suppression of both vascular access type measures under Measure Suppression Factor 1.

TABLE 17: Regression Slopes for Monthly Measure Rates in 2019 and Afterwards

Measure	(a) Slope 2019	(b) Slope 7/2020 – 12/2020	a vs. b p-value	(c) Slope 1/2020 – Dec-21	a vs. c p-value	(d) slope 2021	a vs. d p-value
Fistula rate	-0.0212	-0.0366	0.742	-0.0967	<0.001	-0.1068	<0.001
Catheter rate	0.0373	-0.003	0.162	0.1129	<0.001	0.1381	<0.001

TABLE 18: Unadjusted Fistula Rates, January 2018 - March 2022

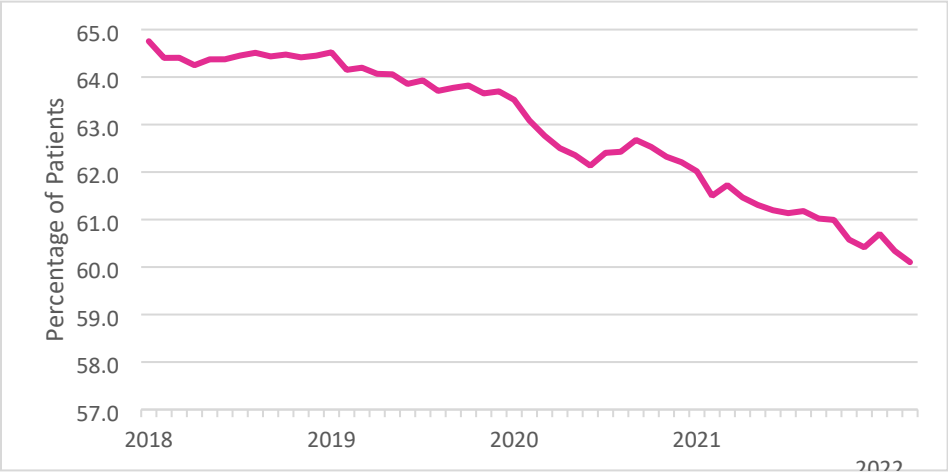
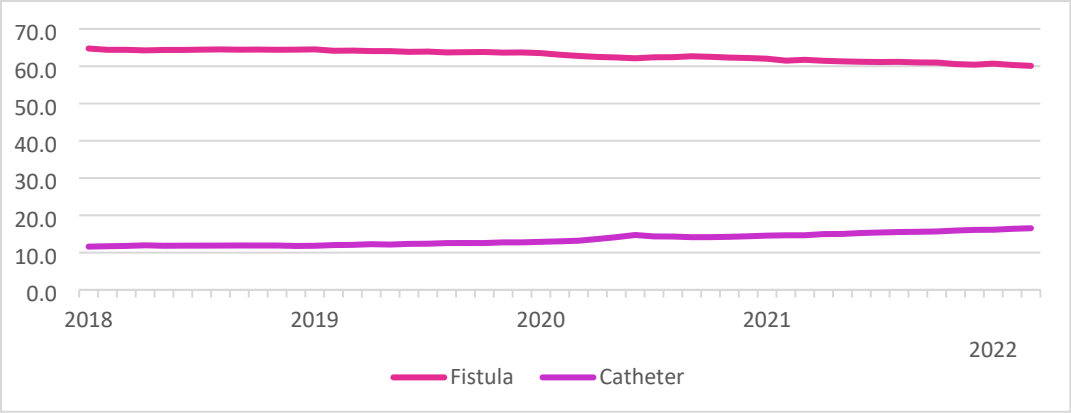


TABLE 19: Vascular Access Type Unadjusted Rates, January 2018 - March 2022



Although we did not propose suppression of the Standardized Fistula Rate measure in the CY 2023 ESRD PPS proposed rule, we believe that the circumstances caused by the COVID-19 PHE that have significantly affected the Long-Term Catheter Rate clinical measure have also affected Standardized Fistula Rate clinical measure and resulting performance score. The same barriers to surgical care for catheter reduction also prevented patients from receiving surgical care for AV Fistulas. During various times throughout the COVID-19 PHE, vascular access procedures were halted and slowed in many areas around the country as COVID-19 volumes surged. The lack of procedures likely meant that fistulas were not created in many cases. For those patients who received an AV fistula, some were not able to undergo procedures required to assist in the maturation of the fistula. In other instances, patients whose access failed were not

able to access the services to repair them. All of these factors led to an increase in long-term catheter use and a decrease in the placement of fistulas during CY 2021, as indicated by the data shown in Tables 17 and 19 above, resulting in significant deviation in national performance on both measures during the PHE for COVID-19 in PY 2023. Therefore, we believe that suppression of the Standardized Fistula Rate measure in this final rule is appropriate under Measure Suppression Factor 1.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2023. We are also finalizing the suppression of the Standardized Fistula Rate clinical measure for PY 2023. We will also publicly report the data for these measures with appropriate caveats.

e. Suppression of the ICH CAHPS Clinical Measure for PY 2023

In the CY 2023 ESRD PPS proposed rule, we proposed 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 (87 FR 38535 through 38536). We stated that 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 noted that 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 stated our intent to publicly report CY 2021 measure rate data where feasible and appropriately caveated. As we noted in section IV.B.1 of the 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 (87 FR 38531).

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. In the CY 2023 ESRD PPS proposed rule, we noted that our most recent analysis that included Spring 2021 ICH CAHPS data showed a continued deviation in ICH CAHPS scores (87 FR 38535).

The ICH CAHPS clinical measure is scored based on three composite measures and three global ratings.[227] 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.

In the proposed rule, we stated that our most recent data indicated that, although the number of participating facilities that submitted data had increased from pre-COVID-19 levels, the number of completed interviews had dropped dramatically. For example, in Spring and Fall 2019, facilities reported 98,868 and 96,255 completed interviews, respectively. By contrast, in

[227] Groupings of questions and composite measures can be found at https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf.

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 stated our belief 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.[228] 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.[229] Although we noted that there was no specific data regarding the healthcare personnel shortages in facilities, reports indicated that facilities have experienced similar staffing shortages.[230] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[231,232]

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[228] 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/.
[229] https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh
[230] 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.beckershospitalreview.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.
[231] 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.
[232] 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

Additionally, in the proposed rule we noted that 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.[233] Conversely, in that same week, less than 10 percent of hospitals in Washington, D.C., Connecticut, Alaska, Illinois, New York, Maine, Montana, Idaho, Texas, South Dakota, and Utah reported staffing shortages. We stated our belief that these staffing shortages reported by hospitals were 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 believed 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,[234,235] we anticipated 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 stated our belief 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.

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[233] 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).

[234] 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).

[235] Fresenius Medical Care Press Release, Statement regarding COVID-19 related supply and staff shortages. Available at: https://fmcna.com/company/covid-19-resource-center/.

Therefore, we proposed to suppress the ICH CAHPS measure for the PY 2023 ESRD QIP under Measure Suppression Factors 1 and 4.

We welcomed public comment on this proposal. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the ICH CAHPS clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID-19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis including Fall 2021 ICH CAHPS data showed a continued deviation in ICH CAHPS scores, with completed survey numbers declining by more than 20,000 from the previous Spring 2021 survey administration. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID-19 PHE on national performance and justifies suppression of the ICH CAHPS measure under Measure Suppression Factor 1.

Comment: One commenter recommended that CMS not suppress the ICH CAHPS measure because the survey requires no staff time as it is administered outside the dialysis facility. One commenter disagreed with the rationale for suppressing the ICH CAHPS measure under Measure Suppression Factor 4, believing the labor shortages are not solely attributed to COVID-19, but rather a workforce demographic shift.

Response: Although the administration of the survey itself may not require staff time, facilities are scored based on the patient's responses reflecting the patient's experience of care at the facility, the substance of which is significantly impacted by staffing levels and staff capacity to attend to patients. For example, the ICH CAHPS asks patients questions such as, "In the last 3 months, how often did the dialysis center staff spend enough time with you?"[236] We believe that

[236] https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf

patients receiving care at facilities experiencing staffing shortages are more likely to respond negatively to such questions about their experience of care. Although we acknowledge that commenter may be correct in its assessment that overall staffing shortages may not be solely attributed to the COVID-19 PHE, we believe that the PHE was an important catalyst related to the workforce demographic shifts in CY 2021. Since the performance on the ICH CAHPS measure is directly impacted by staffing shortages because it measures the patient's experience of care with regards to facility staff, suppressing the ICH CAHPS measure based on staffing shortages is appropriate under Measure Suppression Factor 4.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the ICH CAHPS measure for PY 2023. We will also publicly report the data with appropriate caveats.

f. Suppression of the PPPW Clinical Measure for PY 2023

In the proposed rule, we proposed 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 (87 FR 38536 through 38537).

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 will 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, in the CY 2023 ESRD PPS proposed rule, we stated that we believed that circumstances caused by the COVID-19 PHE had affected our ability to make reliable national, side-by-side comparisons of facility performance on the PPPW measure. Recent analyses indicated that measure performance had 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 noted that we have since observed a continuous decrease in the levels of PPPW clinical measure performance. We believed this decrease was 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 believed reflects a significant deviation in national performance on the measure. We stated that 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 indicated that the percentage of facilities receiving scores lower than 5 (out of 10; a higher score reflects better performance) had 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 were 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 had 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 stated our belief that the COVID-19 PHE continued to have a significant impact on the PPPW clinical measure during CY 2021.

In the proposed rule, we stated that 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. We noted that not only were 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 were 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 stated our concern 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 believed 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.

In the proposed rule, we stated our belief that the PPPW clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the ongoing COVID-19

PHE had affected measure performance on the current PPPW clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we noted that 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 stated our intent to publicly report PY 2023 data where feasible and appropriately caveated.

We noted that we were currently exploring ways to adjust effectively for the systematic effects of the COVID-19 PHE on the PPPW clinical measure. However, we stated that we were 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 noted that we want to ensure that the measure reflects care provided to ESRD patients and we were 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 welcomed public comment on our proposal to suppress the PPPW clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the PPPW clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID-19 PHE.

Response: We thank commenters for their support. Since the publication of the proposed rule, an updated analysis showed a continued deviation in PPPW clinical measure performance throughout CY 2021. We believe that this updated analysis confirms our earlier concerns regarding the impact of the COVID-19 PHE on national performance and justifies suppression of the PPPW clinical measure.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the PPPW clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

g. Suppression of the Kt/V Dialysis Adequacy Clinical Measure for PY 2023

In the proposed rule, we proposed 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 (87 FR 38537 through 38538). We referred 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, in the CY 2023 ESRD PPS proposed rule we stated that we believed that circumstances caused by the COVID-19 PHE had affected the measure and the resulting TPS (87 FR 38537). 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 noted that we had observed continued deviations in Kt/V clinical measure performance over the past 2 years and we believed that this was 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.[237] The confluence of these factors likely contributed to declines in Kt/V clinical measure performance.

In the proposed rule, we noted that our simulations comparing PY 2022 scoring distributions with estimated PY 2023 scoring distributions showed that the percentage of facilities receiving scores less than 7 (out of 10; a higher score reflects better performance) had

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[237] 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

increased at almost every data point, whereas the percentage of facilities receiving scores higher than 7 had 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,[238] we stated our belief that the COVID-19 PHE continued to have a significant impact on the Kt/V clinical measure during CY 2021.

We noted that our analysis of the available data indicated 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 were concerned that facilities in different regions of the country had 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 noted that our scoring simulations indicated 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 believed 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 scoring and payment adjustment purposes.

In the proposed rule, we stated our belief that the Kt/V Dialysis Adequacy clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the ongoing COVID-19 PHE had affected measure performance on the current Kt/V Dialysis

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[238] 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.

Adequacy clinical measure such that we would not be able to score facilities fairly or equitably on it. Moreover, we noted that 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 stated our intent to publicly report PY 2023 data where feasible and appropriately caveated.

We noted that we were 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 were 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 welcomed public comment on our proposal to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for our proposal to suppress six measures for PY 2023, including our proposal to suppress the Kt/V Dialysis Adequacy clinical measure. Several commenters expressed support for the proposed measure suppression because national performance has been distorted due to the impact of the COVID-19 PHE. One commenter expressed support for our proposal to suppress the Kt/V Dialysis Adequacy clinical measure, noting that the PHE significantly limited the availability of vascular access procedures and many of the limitations that contributed to this persist today, including staffing shortages, fewer locations which has resulted in more blood stream infections, hospitalizations, and mortality.

Response: We thank commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023. We will also publicly report the data with appropriate caveats.

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).

In the CY 2023 ESRD PPS proposed rule, we stated that 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 (87 FR 38538). In addition, we discussed that 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.[239] We noted that 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. To account for case mix among facilities, the current risk adjustment approach for these measures included covariates for clinical comorbidities that are relevant and have relationships with the outcome, for example patient history of diabetes or obesity. Therefore, to adequately account for patient case mix, we stated that we were further modifying the technical measure specifications for the SHR and SRR measures to include a covariate adjustment for patient history of COVID-19. We stated that we believed these changes were technical in nature because they did not substantively change the measures themselves and, therefore, were not required to be implemented through rulemaking.

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[239] 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.

In the proposed rule, we stated that 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 proposed to convert the STrR reporting measure to a clinical measure beginning with PY 2025. In the proposed rule, we noted that we were 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 announced in the 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).

The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for including a covariate to adjust for patient history of COVID-19 in the SHR and SRR measures, noting the significant impact of the COVID-19 PHE on these measures. A few commenters recommended that CMS include the adjustment before PY 2025 if possible.

Response: We thank the commenters for their support. Although we considered implementing the technical measure specification updates before PY 2025, we ultimately concluded that PY 2025 was the earliest year feasible for including the covariate adjustment due to data collection timelines.

Comment: One commenter requested that CMS provide more information about the measures' technical specifications and how patient information regarding COVID-19 may be

obtained. One commenter requested that CMS make available supporting analytics so that interested parties may review the impact of such a covariate on model performance.

Response: We will provide more information about the measures' technical specifications, including the updated specifications for the SHR and SRR clinical measures that include the covariate adjustments, in the CMS ESRD Measures Manual for the 2023 Performance Period, which will be available following publication of the CY 2023 ESRD PPS final rule at https://www.cms.gov/files/document/esrd-measures-manual-v80.pdf. As discussed in the Measures Manual, patient information regarding COVID-19 may be obtained from Medicare claims. We will determine the feasibility of making supporting analytics available for interested parties to review to model the impact of such a covariate on a facility's performance.

C. Updates to the Performance Standards Applicable to the PY 2023 Clinical Measures

In the CY 2023 ESRD PPS proposed rule (87 FR 38538), we stated that 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). We noted that under this policy, CY 2021 is currently the performance period and CY 2020 is the baseline period for the PY 2023 ESRD QIP. However, we also stated that 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, in the CY 2023 ESRD PPS proposed rule, we stated that we were concerned that it would be difficult to assess performance standards for PY 2023 based on partial year data. We noted that our preliminary analysis indicated 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 stated that 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 stated that we continued 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 proposed 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 stated our belief that using CY 2019 data for performance standard setting purposes is appropriate. We also proposed to amend 42 CFR 413.178(d)(2) to reflect both our proposed updates applicable to the PY 2023 performance standards, as well as our previously finalized update to the PY 2024 performance standards.

We welcomed public comments on this proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to use CY 2019 data for PY 2023 performance standards, noting that data collected during the COVID-19 PHE have been skewed. One commenter also supported the proposal to use CY 2019 data to calculate

PY 2023 performance standards due to the impact of the shift to the EQRS data system. One commenter expressed support for our proposal to calculate performance standards for PY 2023 using CY 2019 data but emphasized that CY 2019 data does not reflect the impacts of the COVID-19 PHE on facilities.

Response: We thank commenters for their support. We acknowledge the commenter's observation that CY 2019 data does not reflect the impacts of the COVID-19 PHE on facilities. However, we note that one of the reasons we adopted our measure suppression policy for the duration of the COVID-19 PHE was to help minimize the impacts on performance standards for certain measures that have been significantly affected by the COVID-19 PHE, which we believe will improve the comparability of pre-COVID-19 data from CY 2019 for purposes of calculating PY 2023 performance standards.

Comment: A few commenters noted the difficulty in creating reasonable benchmarks when comparing a facility's performance during the COVID-19 PHE to performance before the COVID-19 PHE and expressed concern that using pre-pandemic CY 2019 data as a baseline for assessing COVID-19 era data is not an appropriate comparison. One commenter pointed out the impact of measure suppressions on the number of clinical measures eligible for PY 2023 scoring. One commenter stated that comparing PY 2023 performance using CY 2019 baseline data would be inappropriate because the COVID-19 PHE has resulted in decreased patient adherence to treatment and has increased the complexity of ESRD patient care. One commenter expressed concern with CMS's proposal to use CY 2019 as the baseline year for the PY 2023 ESRD QIP because the combination of the COVID-19 PHE and CMS's focus on home dialysis has impacted the mix of patients at in-center ESRD facilities, which the commenter believes would make it difficult to compare performance in CY 2019 to performance in 2021. This commenter encouraged CMS to evaluate the impact of the COVID-19 PHE and increases in home dialysis use on the individual quality measures and adjust performance targets accordingly. One commenter recommended that CMS consider alternative approaches for updating the

performance standards for PY 2023, such as suspending use of a baseline comparison this year and re-establish a new "post-COVID" baseline next year using the CY 2021 data or simulating early COVID-19 PHE data using 2019 data and then using these data as the baseline for PY 2023.

Response: We appreciate the commenters' concerns. We believe that the use of CY 2019 data as a baseline for assessing COVID-19 era data is an appropriate comparison in light of our measure suppression policy and the suppression of individual measures thereunder. We adopted our measure suppression policy to minimize the impact of the COVID-19 PHE on facility performance, and for PY 2023, we are suppressing certain measures that we believe were significantly impacted by the COVID-19 PHE. We did not suppress measures that we believe were not significantly impacted by the COVID-19 PHE. Given our determinations that these measures were not significantly impacted by the COVID-19 PHE, we believe that performance on these measures is generally comparable to CY 2019 performance, and therefore we believe those measures are appropriate to include in the calculation of PY 2023 performance standards for scoring purposes as comparable to CY 2019 pre-pandemic data. We note that this is a temporary update to our performance standards calculations made in response to an unprecedented PHE, and the impact is limited to those few clinical measures for which measure suppression was not warranted for PY 2023. We believe these updates are necessary to mitigate the impact of the ECE that CMS granted in response at the beginning of the COVID-19 PHE, as well as the COVID-19 PHE itself, on PY 2023 and PY 2024 performance standards calculations. However, we intend to resume our previously finalized performance standards methodology beginning with PY 2025, which will consist of "post-COVID-19" measure data. We appreciate that suppressed measures may have an impact on TPS scores for PY 2023. However, we believe that it is appropriate to score facilities on non-suppressed measures. Although the recalculated mTPS for PY 2023 may be higher, we believe that fewer facilities will be penalized as a result, particularly given that we are finalizing suppression of the Standardized Fistula Rate clinical

measure for PY 2023, which we discuss in section IV.B.2.d of this final rule. We are finalizing for suppression the measures which we have identified as being significantly impacted by the COVID-19 PHE in CY 2021 for PY 2023. We also note that rapid or unprecedented changes to patient case volumes or facility-level case mix, either due to decreased adherence to treatment or changes to dialysis modality as a result of the COVID-19 PHE, would be considered for measure suppression under Measure Suppression Factor 4. Our analyses indicate that the patient case volumes and facility-level case mix were not significantly impacted in those measures that we are not suppressing for PY 2023 and therefore does not inhibit the use of CY 2019 data as the baseline for purposes of calculating PY 2023 performance standards. Finally, we appreciate the commenter's recommendations for alternative approaches to PY 2023 performance standards, but believe that our proposed approach is the most feasible option at this time.

Final Rule Action: After considering public comments, we are finalizing our proposal to calculate the performance standards for PY 2023 using CY 2019 data. We are also finalizing our proposal to amend 42 CFR 413.178(d)(2) to reflect both our finalized updates applicable to the PY 2023 performance standards, as well as our previously finalized update to the PY 2024 performance standards.

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.

In the CY 2023 ESRD PPS proposed rule, we noted that hospitalization and readmission rates vary across facilities even after adjustment for patient characteristics, suggesting that hospitalizations and readmissions might be influenced by facility practices (87 FR 38539). 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 stated that 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). In the CY 2023 ESRD PPS proposed rule, we announced that 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 (87 FR 38539). We noted that interested parties had previously expressed

concern that the SHR clinical measure and the SRR clinical measure were difficult to interpret and track facility performance over time when expressed as ratios, and had recommended expressing those ratios as rates when scoring. We stated that although there are widespread national improvements in hospitalization rates and readmission rates, individual facilities may not see 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. We noted that another concern interested parties raised was that the ratios were difficult to understand and it was difficult to determine how to use these ratios for quality improvement efforts.

In light of these concerns, we stated that we were 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. We noted that, 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 stated our belief that these changes were technical in nature because they did not substantively change the measures themselves and, therefore, were 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. We noted that 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. We stated that these trends showed 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 did 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, we stated that 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 stated our belief that expressing the measure results as 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, we noted that 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.[240] We provided the currently finalized performance standards for the PY 2024 SHR and SRR clinical measures in Table 16 of the proposed rule, and the revised PY 2024 performances standards for the updated SHR and SRR clinical measures in Table 17 of the proposed rule (87 FR 38540). They are described in Table 20 and Table 21 in this final rule.

TABLE 20: 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: SRR, SHR: 2019 Medicare claims.

TABLE 21: 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: SRR, SHR: 2019 Medicare claims.

We welcomed public comments on this technical update. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for expressing SHR and SRR results as rates, noting that this will allow for better year-over-year comparability at the facility level. A few commenters expressed appreciation for the technical updates because they will help to

[240] 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

increase providers' and patients' understanding of the measures and will provide a clearer picture of facility performance.

Response: We thank commenters for their support.

Comment: A few commenters recommended that CMS use a consistent denominator to allow for comparability year-over-year at the facility level so that facilities may take steps to improve their performance. A few commenters recommended that CMS adopt the adjustment factor used in the Star Rating Program, which would translate the adjusted rates in the performance year to the same scale as those in the baseline year. These commenters expressed the belief that this approach will help with year-over-year comparability. One commenter expressed concern that SHR and SRR rates may be difficult to interpret due to a lack of understanding of how the denominator is calculated and inability to understand actual facility performance.

Response: As described in the proposed rule, the methodology for converting ratios to rates that we will move to in the ESRD QIP is equivalent to the methodology used in Dialysis Facility Compare (DFC) reporting. Specifically, in the Star Rating calculation under the DFC program, the ratio for the performance year is multiplied by the adjustment factor (national rate for performance year / national rate for the base year). In both the ESRD QIP and the DFC, this methodology results in rates that give credit for national changes in additional to individual facility changes that differ from the national rate change.

Regarding the comments about interpretability of the measure calculations, we note that the SHR and SRR have been used in public reporting and the ESRD QIP for multiple years. Both the DFC and the ESRD QIP programs have descriptions of how the measure is calculated and how to interpret the measure results for a given dialysis facility's results. Information that would help with understanding how the measures are calculated, such as the inclusion of various risk-adjustments and other factors contributing to denominator calculations, is generally available as part of the public displays and other information tools that CMS makes publicly

available. Given the multiple sources of information available at various levels of detail, we believe that interpretation of results for both the SHR clinical measure and the SRR clinical should be achievable for most or all interested parties.

Comment: One commenter recommended that this policy apply to other standardized ratio measures as well.

Response: We thank the commenter for its recommendation, and note that we are incorporating a similar methodology as part of our proposal to convert the Standardized Transfusion Ratio (STrR) reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule.

E. 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 the proposed rule, we also proposed to adopt a COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) reporting measure beginning in PY 2025 (87 FR 38542 through 38544). In section IV.E.1.b of the proposed rule, we proposed to convert the STrR reporting measure to a clinical measure beginning in PY 2025 (87 FR 38544 through 38545), and in section IV.E.1.c of the proposed rule, we proposed to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025 (87 FR 38545 through 38546). These measures are described in Table 18 in the proposed rule (87 FR 38541), and are described in Table 22 in this final 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.[241]

[241] https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf.

TABLE 22: 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 the 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 Vaccination Coverage among Healthcare Personnel (HCP), 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 final rule.
**We are finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule.
***We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.
****We are finalizing our proposal to adopt the COVID-19 Vaccination Coverage among HCP reporting measure beginning in PY 2025, as discussed in section IV.E.1.a of this final rule.

We discuss our proposal to adopt the COVID-19 Vaccination Coverage among 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. Adoption of the COVID-19 Vaccination Coverage among HCP Reporting Measure Beginning with the PY 2025 ESRD QIP

(1) Background

On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19,[242] caused by a novel coronavirus, SARS-CoV-2. COVID-19 is a contagious respiratory infection[243] 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.[244]

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.[245]

According to available data, COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth, and in some circumstances may contaminate surfaces they touch.[246] According to the CDC, those at greatest risk of

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[242] 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.
[243] 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.
[244] Ibid.
[245] https://covid.cdc.gov/covid-data-tracker#datatracker-home.
[246] Centers for Disease Control and Prevention. (2022). How COVID-19 Spreads. Accessed on October 16, 2022 at: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.

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.[247] 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 HCP and patients, or from patient to patient, given the close contact that may occur during the provision of care.[248] The CDC has emphasized that health care settings can be high-risk places for COVID-19 exposure and transmission.[249]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID-19 and ultimately help restore societal functioning.[250] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID-19 vaccine in the U.S.[251] Subsequently, FDA issued EUAs for additional COVID-19 vaccines[252] and, after a rigorous review process, granted approval to two vaccines.[253]

In the CY 2023 ESRD PPS proposed rule, we stated our belief that it is important to incentivize and track HCP vaccination for COVID-19 in facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of these

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[247] 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.
[248] 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.
[249] 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.
[250] 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.
[251] 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 October 12, 2022).
[252] 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 October 12, 2022); 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 May 5, 2022). U.S. Food and Drug Administration. (2022). Novavax COVID-19 Vaccine, Adjuvanted EUA Letter of Authorization. Available at https://www.fda.gov/media/159902/download (as reissued September 12, 2022).
[253] 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.

facilities to continue serving their communities throughout the PHE and beyond (87 FR 38542). We recognized the importance of COVID-19 vaccination, and noted that we 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). In the proposed rule, we stated our belief 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.[254] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[255] and we noted that we believe that HCP COVID-19 vaccination in facilities could similarly

[254] 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.
[255] 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.

increase uptake among that patient population. We also stated our belief 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. We noted that 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.[256,257] 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 Vaccination Coverage among HCP 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.[258, 259]

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

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[256] 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

[257] 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

[258] 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.

[259] 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

approved vaccine for COVID-19. A completed primary series vaccination course may require one or more doses depending on the specific vaccine used.[260,261] We stated that 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 Vaccination Coverage among HCP 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.[262] When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed measures on the MUC List including the COVID-19 Vaccination Coverage among HCP 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.[263] 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.[264]

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[260] 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.
[261] Centers for Disease Control and Prevention. The National Healthcare Safety Network (NHSN) Safety Manual: Weekly COVID-19 Vaccination Protocol for Healthcare Personnel. Accessed October 14, 2022 at: https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.
[262] 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.
[263] Measure Applications Partnership. MAP Preliminary Recommendations 2020-2021. Accessed on January 24, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.
[264] Ibid.

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[265] 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.[266] 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.[267] 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.[268]

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 Vaccination Coverage among HCP measure, which showed that the numerator data should be feasible and reliable.[269] 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

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[265] Ibid.
[266] Ibid.
[267] Measure Applications Partnership. 2020-2021 MAP Final Recommendations. Accessed on February 23, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.
[268] Measure Applications Partnership. 2020-2021 MAP Final Recommendations. Accessed on February 23, 2021 at: http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.
[269] 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.

the CDC through the federal pharmacy partnership program for delivering vaccination to LTC facilities. In the proposed rule, we noted that these two data collection systems are independent but show high correlation. In initial analyses of the first month of 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.[270] 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, in the proposed rule we stated our belief that 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.

In the proposed rule, we noted that the proposed COVID-19 Vaccination Coverage among HCP measure was not NQF endorsed. The CDC, in collaboration with CMS, submitted the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure was not NQF-endorsed at the time we issued the proposed rule, we stated that we considered whether there were other available measures that assess COVID-19 vaccination rates among HCP. We noted that we found no other feasible and practical measures

[270] Ibid.

on the topic of COVID-19 vaccination among HCP, therefore the exception in section 1881(h)(2)(B)(ii) of the Act applied. We stated our belief that it was 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 proposed 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.[271] 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 proposed that facilities would collect the numerator and denominator for the COVID-19 Vaccination Coverage among HCP 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, in the proposed rule we stated that we were 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 believed the most recent week's data would provide the most currently available information. For example, if first and third week data are submitted,

[271] 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.

third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we proposed 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 stated that 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 the proposed rule (87 FR 38543), 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 welcomed 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. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to add the COVID-19 Vaccination Coverage among HCP reporting measure to the ESRD QIP beginning with PY 2025. Several commenters expressed support for CMS's proposal to adopt the COVID-19 HCP Vaccination Coverage among HCP reporting measure, noting the importance of incentivizing and tracking HCP vaccination to protect health care workers, patients, and caregivers. A few commenters noted that although facilities have worked to reduce the risk of COVID-19 through vaccination efforts, more support from federal agencies is needed to address significant opposition to vaccines that still exists in certain parts of the country. One commenter supported inclusion of the COVID-19 Vaccination Coverage among HCP reporting measure in the PY 2025 ESRD QIP to ensure consistency with other CMS programs.

Response: We thank these commenters for their support.

Comment: Although several commenters expressed support conceptually for the COVID-19 Vaccination Coverage among HCP reporting measure because tracking and reporting COVID-19 vaccination rates at facilities is important, these commenters expressed concern that the measure was not appropriate for the ESRD QIP. One commenter noted that currently all eligible dialysis HCP are required to be vaccinated against COVID-19 under CMS's Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule. A few commenters recommended that CMS include the COVID-19 Vaccination Coverage among HCP reporting measure in Dialysis Facility Compare (DFC). A few commenters noted that facilities are already required to report vaccination data and expressed concern that including a COVID-19 Vaccination Coverage among HCP reporting measure in the ESRD QIP would be duplicative and would impose an unnecessary reporting burden for facilities. A few commenters stated that the COVID-19 Vaccination Coverage among HCP measure was not appropriate for the ESRD QIP because they believe that tracking HCP vaccination status will not improve quality of ESRD care.

Response: We thank commenters for their input. We believe that the COVID-19 Vaccination Coverage among HCP reporting measure is appropriate for inclusion in the ESRD QIP. Although all eligible HCP are required to be vaccinated against COVID-19 under CMS's Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (86 FR 61555), including the COVID-19 Vaccination Coverage among HCP reporting measure in the ESRD QIP will provide patients and their caregivers with information regarding the rates of HCP COVID-19 vaccination at individual facilities, and such information will help them make informed treatment decisions. We further believe that the COVID-19 Vaccination Coverage among HCP reporting measure will not create a new, ESRD QIP specific reporting burden for the majority of facilities because they are already reporting the same information via the ESRD Network program or to comply with state reporting requirements. To the extent the adoption of this measure for the ESRD QIP imposes a new reporting burden on some facilities, we believe the importance of collecting and reporting data on COVID-19 vaccination coverage among HCP is sufficiently

beneficial to outweigh this burden. We are also collaborating with the CDC to minimize reporting burden to the extent feasible where facilities separately report the data to the CDC for other monitoring purposes. Finally, we strongly believe that tracking HCP vaccination status will have an impact on the quality of ESRD care. ESRD patients are more vulnerable to experiencing complications as a result of a COVID-19 infection. We believe that encouraging HCP vaccination against COVID-19 will help to protect HCP and the ESRD patients they care for by reducing the risk of COVID-19 transmission in facilities.

Comment: A few commenters requested that CMS define HCP for purposes of this measure to exclude HCP outside an organization's workforce, noting difficulties in tracking vaccination rates among HCP who are not in the scope of a provider's workforce. One commenter recommended that CMS allow facilities to exclude from the count staff with no direct in-person patient contact at any time. One commenter recommended that CMS consider allowing an attestation of vaccination status from the employer of contracted personnel to satisfy reporting obligations under the COVID-19 Vaccination Coverage among HCP reporting measure. This commenter expressed concern with the proposed COVID-19 Vaccination Coverage among HCP reporting measure because the required level of detail for NHSN reporting is greater than the detail it receives from such contractors regarding vaccination status. The commenter also expressed concern that its internal systems lack capacity to collect and store vendor data regarding individual vaccination status, noting that storing data for outside contractors increases the risk of data breaches, and compliance with the NHSN's level of specificity would require additional resources that may detract from the quality of patient care. Finally, the commenter noted that CMS has access to contracted vendor data through other channels.

Response: We acknowledge commenters' concerns regarding reporting burden associated with the specifications of this measure specifically around the definition of HCP. We note that given the highly infectious nature of the virus that causes COVID-19, we believe it is

important to encourage all personnel within the facility, regardless of patient contact, role, or employment type, to receive the COVID-19 vaccination to prevent outbreaks within the facility which may affect resource availability and have a negative impact on patient access to care. We also note that CDC's guidance for entering data requires submission of HCP count at the facility level, and the measure requires reporting consistent with that guidance.[272] The decision to include or exclude HCP from the facility's HCP vaccination counts should be based on whether individuals meet the specified NHSN criteria and are physically working in a location that is considered any part of the facility that is being monitored.[273] Additionally, the CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID-19 Vaccination among Healthcare Personnel to help facilities log and track the number of HCP who are vaccinated for COVID-19. Facilities would enter COVID vaccination data for each HCP in the tracking worksheet, and select a reporting week, and the data to be entered into the NHSN will automatically be calculated on the Reporting Summary.[274]

Comment: A few commenters sought clarification on how CMS will define "complete vaccination course" as well as the length of time CMS will give HCP to get boosters or new vaccines.

Response: HCP should be counted as vaccinated if they received COVID-19 vaccination any time from when it first became available in December 2020. A completed vaccination course, which is defined for purposes of this measure as the primary vaccination series, may require one or more doses depending on the specific vaccine used. The NHSN application automatically calculates the total value for "Any completed COVID-19 vaccine series." This is the cumulative number of HCP who completed any COVID-19 vaccine series (dose 1 and dose 2 of COVID-19 vaccines requiring two doses for completion or one dose of COVID-19 vaccines

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[272] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID-19 Vaccination Coverage. Available at: https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.
[273] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed September 7, 2022 at: https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf.
[274] Data Tracking Worksheet for COVID-19 Vaccination among Healthcare Personnel, available at: https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.

requiring only one dose for completion) at the facility or elsewhere (for example, a pharmacy). For surveillance purposes, facilities are required to enter data in the NHSN application on the number of HCP who have received an additional or booster dose of the COVID-19 vaccine.[275] As vaccination protocols continue to evolve, we will work with the CDC to update relevant measure specifications as necessary.

Comment: A few commenters recommended that CMS exclude from the measure any HCP who have been granted a religious belief exemption under an individual facility's policies.

Response: The measure denominator excludes HCP who were determined to have a medical contraindication, defined as: severe allergic reaction (for example, anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine or an immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. Religious or personal beliefs are not approved exemptions for purposes of the COVID-19 Vaccination Coverage among HCP reporting measure. Under the measure specifications, any HCP who decline vaccination because of religious or philosophical exemptions should be categorized as declined vaccination.

Comment: One commenter recommended that CMS seek NQF endorsement for this measure and develop a validation process for the measure prior to inclusion in the ESRD QIP.

Response: Although NQF endorsement was pending at the time we issued the proposed rule, the NQF endorsed this measure in July 2022.[276] We will also work with the CDC on developing a validation process.

Comment: One commenter expressed concern that the reporting frequency would increase burden and therefore recommended that reporting be required no more than twice per year.

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[275] https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf.

[276] National Quality Forum, QPS Tool. Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel (NQF #3636). July 26, 2022. Available at https://www.qualityforum.org/QPS/QPSTool.aspx.

Response: We disagree that the reporting frequency is overly burdensome and that facilities should report twice per year instead of quarterly because we believe that important public health initiatives outweigh this burden. We proposed that facilities report at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN HPS Component before the quarterly deadline. We note that the majority of facilities are already reporting these data on a weekly or monthly basis under the ESRD Network program or due to existing state reporting requirements. We proposed that for each quarter, the CDC would calculate a single quarterly COVID-19 HCP vaccination coverage rate for each facility by taking the average of the data from the three weekly rates submitted by the facility for that quarter. CMS will publicly report each quarterly COVID-19 HCP vaccination coverage rate as calculated by the CDC. Consistent monthly vaccination reporting by facilities will help patients and their caregivers identify facilities that have potential issues with vaccine confidence or slow uptake among staff.

Final Rule Action: After considering public comments, we are finalizing our proposal to add the COVID-19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025.

b. 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 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. In the CY 2023 ESRD PPS proposed rule, we stated our belief that these updates

would result in identification of a greater number of inpatient transfusion events compared to the previously implemented STrR clinical measure (87 FR 38545). In addition, we noted that 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 proposed to convert the STrR reporting measure to the revised STrR clinical measure using the revised specifications that were endorsed by the NQF (87 FR 38545). We stated our belief 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 also proposed 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 also proposed to express the proposed STrR clinical measure as a rate, rather than as a ratio. We stated our belief 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, in the proposed rule we stated our belief 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 the CY 2023 ESRD PPS proposed rule (87 FR 38539 through 38540).

We welcomed public comment on our proposals. The comments we received and our responses are set forth below.

Comment: One commenter supported our proposal to convert the STrR reporting measure to a clinical measure for PY 2025. However, this commenter urged CMS to do so only until the STrR measure can be replaced with a measure of hemoglobin (Hb) <10 g/dL measure, which commenter stated is supported by current evidence as the most actionable and operationally feasible anemia management measure for dialysis providers.

Response: We thank the commenter for its support. Although we are not aware of current data that clearly establishes a minimum hemoglobin threshold that reliably maximizes the primary outcomes of survival, hospitalization, and quality of life for most patients, we will reassess the feasibility of replacing the STrR clinical measure with a hemoglobin measure as part of our future measure development work as new evidence becomes available.

Comment: One commenter requested that CMS provide more information regarding the proposed STrR clinical measure, including the scoring methodology. One commenter requested that CMS increase transparency in transfusion data by providing facilities with a monthly transfusions data set to model the measure and make improvements based on that data.

Response: The STrR clinical measure is a ratio (which, like the SHR and SRR clinical measures, would be expressed as a rate) of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window. This measure is calculated as a ratio but can also be expressed as a rate. We are finalizing this scoring methodology in this final rule as part of the finalized STrR clinical

measure and will provide more details regarding technical specifications in the updated Measures Manual.

We appreciate commenter's request for increased transparency in transfusion data and will take its recommendation to provide facilities with a monthly transfusions data set to model the measure and make improvements based on that data under consideration.

Comment: Several commenters did not support our proposal to convert the STrR reporting measure to a clinical measure, recommending that the STrR remain a reporting measure. Several commenters expressed concern that facilities will be unfairly penalized as a result of our proposal to convert the STrR reporting measure to a clinical measure, noting that although patients often receive non-ESRD-related transfusions, hospitals will code non-ESRD transfusions erroneously due to differences in coding practices. A few commenters requested that CMS release data showing how previous coding and validity concerns were addressed, noting that measure inaccuracies could negatively impact patient care. Several commenters remained concerned about the STrR's continued use in the ESRD QIP because facilities do not have access to transfusion data and may have difficulty obtaining the information. Several commenters noted that the measure tracks hospital decision-making rather than facility activities and that facilities often do not have access to STrR information because it is maintained by hospitals. Without access to this relevant measure-related data, commenters stated that facilities are not able to act to improve measure performance. One commenter expressed concern that converting the STrR reporting measure to a clinical measure may discourage facilities from treating patients with an increased likelihood of transfusion.

Response: We believe that these concerns expressed by commenters have been mitigated by the recent NQF-endorsed revisions to the STrR clinical measure. For hospital inpatients, the previous version of the STrR clinical measure relied on a restricted transfusion event identification algorithm. The measure utilized only those reported transfusion events that include ICD procedure codes, ICD procedure codes with revenue center codes, or value codes.

For the revised STrR clinical measure that is currently NQF-endorsed, 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. This revision will result in identification of a greater number of inpatient transfusion events compared to the currently implemented STrR. In addition, the revision will effectively mitigate a provider coding bias that was exacerbated by the conversion from ICD-9 to ICD-10 code sets in late CY 2015. Identification of outpatient transfusion events is identical in the two STrR versions, as the ICD-9 to ICD-10 transition does not impact outpatient transfusion claims submission (outpatient claims rely on HCPCS procedure codes instead). The NQF website's QPS Tool is a public tool which allows users to search for information on all endorsed measures, including the STrR clinical measure.[277] We refer commenters to this website for further information on how previous coding and validity concerns in the previous version of the STrR clinical measure were addressed in the revised STrR clinical measure. Additional information regarding the STrR clinical measure is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP.

Although we appreciate commenters' concerns regarding the role of hospitals in the STrR clinical measure, we note that hospitals and facilities often work together to coordinate aspects of ESRD patient care. Anemia is a complication of end-stage renal disease that can be avoided if a patient's dialysis facility is undertaking proper anemia management. When anemia is not managed, patients are subjected to unnecessary transfusions that increase morbidity and mortality. The STrR measure is calculated using data reported by hospitals because poor anemia management results in transfusions that most often occur in hospitals and not dialysis facilities.

Comment: A few commenters expressed concern regarding the proposed STrR clinical measure, and recommended replacing it with the Hgb<10 g/dL measure. A few commenters strongly urged CMS to adopt a Hgb<10 g/dL measure, stating that such a measure will more

[277] https://www.qualityforum.org/QPS/QPSTool.aspx

accurately reflect a facility's anemia management performance. These commenters also noted that the Hgb<10 g/dL measure would provide more transparency than the STrR measure so that facilities have more actionable information regarding anemia management, resulting in a greater positive effect on patient care and outcomes. A few commenters further noted that the STrR has not had much of an impact on hemoglobin levels and recommended that CMS prioritize finding a more appropriate anemia management measure as it shifts toward more patient-reported outcome measures.

Response: As we discussed in the CY 2020 ESRD PPS final rule, use of a hemoglobin threshold measure has been previously considered and was not implemented based on several concerns (84 FR 60722). First, studies reporting results of anemia management in chronic dialysis settings typically result in hemoglobin distributions with relatively large outcome variation, creating concern that attempts at achievement of a specific target will result in a substantial minority of treated patients either well above or below the target at any point in time. Given the significant concerns about potential clinical risks of overtreatment with Erythropoietin stimulating agents (ESAs), implementation of a hemoglobin threshold could result in increased risk of ESA-related complication for the subset of patients above the threshold. One major consequence of under treatment is increased transfusion risk. Emphasis on minimizing avoidable transfusions in this population focuses on avoiding a major consequence of under-treatment without explicitly contributing to the risks associated with over-treatment with ESAs. This approach is consistent with the Food and Drug Administration (FDA) guidance for use of ESAs in this population. In addition, the available literature has not clearly established a minimum hemoglobin threshold that reliably maximizes the primary outcomes of survival, hospitalization, and quality of life for most patients. However, we will review new evidence as it becomes available to reassess the feasibility of replacing the STrR clinical measure with a hemoglobin measure as part of our future measure development work.

Final Rule Action: After considering public comments, we are finalizing our proposal to convert the STrR reporting measure to a clinical measure. We are also finalizing our proposal 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. We are also finalizing our proposal to express the STrR clinical measure results as a rate.

c. Conversion of 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 the CY 2023 ESRD PPS proposed rule, we noted that 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 (87 FR 38545). We noted that many interested parties 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.

Considering these persistent concerns expressed by interested parties, we stated in the proposed rule that we are currently examining the continued viability of the Hypercalcemia clinical measure as part of the ESRD QIP measure set. We also acknowledged 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.[278]

In the proposed rule, we stated that 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 (87 FR 38545). We noted that, 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 stated our belief that it was possible that certain outliers in the 90th percentile could have skewed the statistically distinguishable part of the topped out analysis. In other

[278] 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.

words, although the Hypercalcemia clinical measure was not considered topped out based on our previously adopted methodology, we believed that it was very close to being topped out based on the available data and were concerned that small differences in measure performance may disproportionately impact a facility's score on the measure.

Therefore, we proposed 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 also proposed to update the scoring methodology so that facilities that meet previously finalized minimum data and eligibility requirements would receive a 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, we stated that the Hypercalcemia reporting measure would be in our Reporting Measure Domain, which we discussed in section IV.E.2 of the proposed rule.

We welcomed public comments on our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning in PY 2025. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to convert the Hypercalcemia measure to a reporting measure, noting that the measure is topped out and does not provide meaningful information to patients or care providers. One commenter supported the proposal to convert the Hypercalcemia clinical measure into a reporting measure, noting that this measure is important for monitoring but that facilities cannot control their performance on the measure. One commenter supported conversion of the Hypercalcemia clinical measure to a reporting measure because it will reduce burden for a condition in which interventions are beyond providers' control.

Response: We thank the commenters for their support.

Comment: Several commenters recommended that CMS replace the hypercalcemia measure with the Serum Phosphorus measure, noting that it is a more informative and effective measure of bone mineral metabolism and that physicians rely on the serum phosphorus measure to make clinical decisions. One commenter recommended replacing the Hypercalcemia measure with the Serum Phosphorus measure in ESRD QIP because it better aligns with the requirements of the Protecting Access to Medicare Act of 2014 (PAMA) for CMS to include measures of relevance for oral-only drugs in the ESRD QIP, and it encourages coordination of care among an ESRD patient's providers to ensure that phosphorus levels are regularly assessed for purposes of phosphorus management. One commenter recommended that CMS replace the hypercalcemia measure with a new measure of appropriate use of secondary hyperparathyroidism (SHPT) medications to reduce excessive PTH levels according to current clinical guidelines. A few commenters recommended that CMS consider only feasible measures that are more clinically meaningful for purposes of quality improvement.

Response: We thank the commenters for their recommendations and will take them under consideration. As noted in the proposed rule, we are currently examining the continued viability of the Hypercalcemia clinical measure as part of the ESRD QIP measure set and 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.

Comment: A few commenters recommended that CMS remove the Hypercalcemia measure from the ESRD QIP measure set entirely. One commenter recommended that the hypercalcemia measure should be suppressed in the interim while CMS finds a more appropriate measure of bone mineral metabolism. This commenter stated that, although converting Hypercalcemia to a reporting measure would alleviate the measure's impact on a facility's score, a facility should not have to report on a measure that lacks significance.

Response: We are considering the long-term viability of the Hypercalcemia measure and examining possible alternative measures to replace the Hypercalcemia measure in the ESRD QIP. If we do propose to remove the Hypercalcemia measure from the ESRD QIP measure set in future rulemaking, we will also propose to replace it with a different bone mineral metabolism measure. We disagree with the commenter's recommendation to suppress the Hypercalcemia measure in the interim, and note that our measure suppression policy only 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, as guided by the measure suppression factors we have finalized. Our analyses indicate that facility performance on the Hypercalcemia clinical measure was not significantly impacted by the COVID-19 PHE in CY 2021, as the scoring simulations for the Hypercalcemia clinical measure showed that measure performance was consistent with performance from previous years. Our analyses also did not show that there were significant changes in measure performance on the Hypercalcemia clinical measure, proximity between the measure's focus to the health impacts of the COVID-19 PHE, rapid or unprecedented changes in clinical guidelines or care delivery or practice, or significant national shortages or rapid or unprecedented changes in patient-case volumes or facility-level case mix. Therefore, we concluded that suppression of the Hypercalcemia clinical measure is not warranted under any of our previously finalized Measure Suppression Factors. We also disagree that the Hypercalcemia measure lacks significance. Although the Hypercalcemia clinical measure may be close to being topped out, we believe the measure still encourages adequate management of bone mineral metabolism and disease in patients with ESRD and thus is appropriately included in the ESRD QIP measure set at this time.

Final Rule Action: After considering public comments, we are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning with the PY 2025 ESRD QIP.

2. 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.[279] 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

[279] CMS Website, Meaningful Measures Framework. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.

ESRD (79 FR 66214) (that is, the Meaningful Measures Framework priorities, which includes our preferred emphasis on patient outcomes).

In the CY 2023 ESRD PPS proposed rule, we stated that currently, ESRD QIP measures are weighted and distributed across four measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, and Safety (87 FR 38546). 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 we are finalizing in this final 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 proposed 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 noted that we proposed to convert the STrR reporting measure to a clinical measure, as discussed in section IV.E.1.b of the proposed rule, and as a result, we proposed that the proposed STrR clinical measure would be placed in the Clinical Care Measure Domain (87 FR 38546).

We also proposed 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 stated our belief that 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 in the CY 2023 ESRD PPS proposed rule (87 FR 38547), which we include in this final rule as Table 23 and Table 24.

TABLE 23: 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 24: 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 finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule.
**We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.
***We are finalizing our proposal to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this final rule.

We welcomed 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. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for our proposal to create a reporting measure domain and reweight measures and measure domains.

Response: We thank commenters for their support.

Comment: A few commenters expressed concern with our proposal to create a new reporting measure domain and re-weight existing measure domains, stating that CMS should instead aim to reduce the number of measures in the ESRD QIP and weight the remaining measures to align with clinical value and importance to patients so that they are meaningful.

Response: We agree with commenters that the weights should reflect clinical value and meaningfulness to patients, which we took into account in developing our proposal. We believe that the proposed measure domains and weights will provide facilities with more meaningful incentives to improve performance on measures that align with clinical value and importance to patients. Although we aim to minimize facility burden as much as feasible, we disagree that reducing the number of measures in the ESRD QIP should be a goal, absent justification under our previously finalized measure removal policy (83 FR 56983 through 56985). We note that we have developed the ESRD QIP measure set specifically to ensure that facilities focus on the most relevant clinical topics that will lead to improved quality of care and better outcomes for patients.

Comment: A few commenters expressed concern regarding our proposal to update domain weights and our proposal to update individual weights within those domains. One commenter expressed concern with our proposal to weight the reporting measure domain at 10 percent, noting that reporting measures currently account for 18 percent of a facility's TPS. This commenter recommended that the reporting measure domain should be worth at least 18 percent of a facility's total score, emphasizing the critical role of reporting measures in a facility's quality of care provided to patients. One commenter recommended that each measure domain should have equal weight because it would support the CMS National Quality Strategy goal of alignment among value-based purchasing programs and would further highlight the importance of patient experience and person-centered care. One commenter was particularly concerned with the weight of the ICH CAHPS and the STrR, believing that the measures were too heavily weighted and that the resulting TPS would not accurately reflect a facility's performance. One

commenter recommended that CMS weight the Long-Term Catheter Rate measure greater than the Standardized Fistula Rate measure to support a "catheters last" approach to improve patient outcomes. This commenter also recommended that CMS work with the kidney care community to develop more appropriate weights. One commenter expressed support for increasing the PPPW measure weight, but noted that dialysis facilities should be more strongly encouraged to refer clinically appropriate patients for transplant evaluation by strengthening regulatory incentives for the referral source.

Response: Although we will take these recommendations into consideration for future rulemaking, we believe that the proposed Reporting Measure Domain weights are appropriate to support high quality health care on all ESRD QIP measures. We will also take commenters' recommendations regarding specific measure weights into consideration for future rulemaking, but believe that the proposed weights are appropriate at this time to incentivize quality improvement in more actionable clinical measures. That is, we believe it is appropriate to assign greater weights to those clinical measures that have more room for quality improvement and therefore may help to ensure better patient outcomes. We note the ICH CAHPS measure weight will remain the same at 15 percent, which we continue to believe is an appropriate weight for incentivizing facility performance on a measure of a patient's experience of care. Although the STrR clinical measure weight will increase from 10 percent to 12 percent, we believe this incremental increase appropriately reflects the importance of anemia management in the ESRD QIP. We believe a combined vascular access type measure topic, weighted at 12 percent, makes sense to accommodate the different vascular access needs of patients. We appreciate commenter's support for increasing the weight of the PPPW clinical measure and will continue to consider ways to further incentivize transplant referrals where clinically appropriate.

Comment: One commenter expressed concern that changing the weight of ESRD QIP measures may increase burden and confusion among facilities and providers.

Response: We appreciate commenter's feedback, but we disagree that changing the weight would increase burden or confusion among facilities and providers. We believe that changing the weights of ESRD QIP measures as proposed will better inform facilities' ability to improve performance on more actionable clinical measures and will result in more meaningful patient outcomes. In addition, we will engage in education and outreach activities to communicate information about the updated weights as well as other measure and program changes being finalized in this rule.

Comment: One commenter urged CMS to re-base performance for the first year after the COVID-19 PHE to ensure the impact of the PHE is accurately accounted for and that measure performance is accurately assessed going forward. One commenter recommended that CMS should have a reassessment plan for all measures and that home dialysis-only programs be reassessed for measure weights because some current domains would no longer be applicable.

Response: We thank commenters for their suggestions and will take them into consideration for future rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal to create a new Reporting Domain and to update the domains and measure weights used to calculate the TPS, beginning with PY 2025. We are finalizing the proposed domain and measure weights described in Table 24 of this final rule.

3. 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 seven measures we are suppressing for the PY 2023 ESRD QIP, 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. In the proposed rule, we estimated the performance standards for the PY 2025 clinical measures in Table 21 using data from CY 2019, which was the most recent data available (87 FR 38548). We are updating these standards for the non-suppressed measures, using CY 2021 data, in this final rule, in Table 25 below.

TABLE 25: Performance Standards for the PY 2025 ESRD QIP Clinical Measures

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (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%
Standardized Readmission Ratio[a]	34.27	26.97	17.02
NHSN BSI	0.833	0.290	0
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54
Standardized Transfusion Ratio[b]	53.46	29.78	10.75
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 finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule, and have updated the table accordingly in this final rule.

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 EQRS; SRR, SHR: 2019 Medicare claims; STrR: 2021 Medicare claims; Kt/V: 2019 EQRS; Hypercalcemia: 2019 EQRS; NHSN: 2021 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 EQRS and 2019 Organ Procurement and Transplantation Network (OPTN).

In addition, we summarize in Table 26 existing requirements for successful reporting on reporting measures in the PY 2025 ESRD QIP.

TABLE 26: 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.
Hypercalcemia**	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage among HCP***	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 finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule, and have updated this table accordingly.
**We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.
***We are finalizing our proposal to adopt the COVID-19 Coverage among HCP reporting measure beginning in PY 2025, as discussed in section IV.E.1.a of this final 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 27. We did not propose any changes to these eligibility requirements for the PY 2025 ESRD QIP in the proposed rule.

TABLE 27: 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 (Reporting)*	11 qualifying patients	N/A	N/A
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 (Clinical)**	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities 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

Measure	Minimum data requirements	CCN open date	Small facility adjuster
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 Vaccination Coverage among HCP (Reporting)***	11 qualifying healthcare personnel	N/A	N/A

* We are finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule.
**We are finalizing our proposal to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this final rule, and have updated this table accordingly in this final rule.
***We are finalizing our proposal to adopt the COVID-19 Vaccination Coverage among HCP measure beginning in PY 2025, as discussed in section IV.E.1.a of this final 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).

In the proposed rule, we stated that for PY 2025, based on available data, a facility must meet or exceed a mTPS of 55 to avoid a payment reduction (87 FR 38552). We noted that the mTPS estimated in the proposed rule is based on data from CY 2019 instead of the PY 2025 baseline period (CY 2021) because CY 2021 data were not yet available.

We refer readers to Table 25 of this final rule for the PY 2025 finalized performance standards for each clinical measure. We stated in the CY 2023 ESRD PPS proposed rule that

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 of the proposed rule (87 FR 38552). Table 28 of this final rule is a reproduction of Table 24 from the CY 2023 ESRD PPS proposed rule.

TABLE 28: 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%

We stated our intention to update the mTPS for PY 2025, as well as the payment reduction ranges for that payment year, in this CY 2023 ESRD PPS final rule.

We have now finalized the payment reductions that will apply to the PY 2025 ESRD QIP using updated CY 2021 data. The mTPS for PY 2025 will be 55, and the finalized payment reduction scale is shown in Table 29.

TABLE 29: Finalized 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%

F. Updates for the PY 2026 ESRD QIP

1. Continuing Measures for the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS proposed rule, we stated that, under our previously adopted policy, the PY 2025 ESRD QIP measure set would also be used for PY 2026 (87 FR 38552). We did not propose to adopt any new measures beginning with the PY 2026 ESRD QIP.

2. Performance Period for the PY 2026 ESRD QIP

In the CY 2023 ESRD PPS proposed rule, we stated our continued belief that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP (87 FR 38552). 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 did not propose 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

In the CY 2023 ESRD PPS proposed rule, we stated that at the time, we did not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we did not have CY 2021 data (87 FR 38552). We stated our intent to publish these numerical values, using CY 2021 data, in this CY 2023 ESRD PPS final rule. We provide the estimated performance

standards for the PY 2026 ESRD QIP clinical measures, using applicable CY 2021 data, in Table 30 of this final rule.

TABLE 30: Estimated Performance Standards for the PY 2026 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%
Standardized Readmission Ratio[a]	34.27	26.97	17.02
NHSN BSI	0.833	0.290	0
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54
Standardized Transfusion Ratio[b]	53.46	29.78	10.75
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 finalizing our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this final rule, and have updated the table accordingly in this final rule.

[a]Rate calculated as a percentage of hospital discharges
[b]Rate per 100 patient-years
Data sources: VAT measures: 2019 EQRS; SRR, SHR: 2019 Medicare claims; STrR: 2021 Medicare claims; Kt/V: 2019 EQRS; Hypercalcemia: 2019 EQRS; NHSN: 2021 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 EQRS and 2019 Organ Procurement and Transplantation Network (OPTN).

We note that these performance standards may be updated in the CY 2024 ESRD PPS final rule based on CY 2022 data.

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 final rule, we are finalizing our proposals 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 will include these in the performance standards for reporting measures in the PY 2026 ESRD QIP.

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 final rule, we are finalizing our proposal 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 final rule, we are finalizing our proposal to update our scoring methodology as part of our policy to convert the Hypercalcemia clinical measure to a reporting measure beginning with PY 2025. We are also finalizing our proposal to adopt a scoring methodology as part of our policy 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 final 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 final rule, we are finalizing our proposal to add a new Reporting Measure Domain, and we are finalizing our proposed new weights for the four existing measure domains, beginning in PY 2025. We provide the updated measure weights and domains and the TPS for PY 2026 in this final rule in Table 24.

G. Requests for Information (RFI) on Topics Relevant to ESRD QIP

1. Request for Information on Quality Indicators for Home Dialysis Patients

In the proposed rule, we sought public comments on potential indicators of quality for patients who receive dialysis at home to support the use of home dialysis for ESRD patients

where it is appropriate (87 FR 38553 through 38554). While home-based dialysis may not meet the needs of every patient, we stated that 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.[280]

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.[281,282]

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.[283] 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

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[280] ASPE Report, Advancing American Kidney Health, p. 24. Available at *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf*.

[281] Stack AG. Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study. Journal of the American Society of Nephrology. 2002; 13: 1279-1287. Doi 1046-6673/1305-1279.

[282] Miskulin DC, et al. Comorbidity and Other Factors Associated With Modality Selection in Incident Dialysis Patients: The CHOICE Study. American Journal of Kidney Diseases. 2002; 39(2): 324-336. Doi 10.1053/ajkd.2002.30552.

[283] Blagg CR. A Brief History of Home Hemodialysis. Annals in Renal Replacement Therapy. 1996; 3: 99-105.

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.[284]

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.[285] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used HHD.[286] In the proposed rule, we noted 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.[287]

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

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[284] United States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO-16-125). October 2015.
[285] 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.
[286] 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.
[287] National Kidney Foundation. https://www.kidney.org/news/newsroom/fsindex. Accessed 11/15/2021.

operating costs for dialysis providers for providing home dialysis.[288,289,290,291,292]

In the proposed rule, we stated our belief 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.[293, 294, 295, 296, 297] 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,[298] we stated our interest 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 sought comments on strategies to monitor and assess the quality of care delivered to patients who

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[288] Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home hemodialysis modalities compared with facility hemodialysis: A systematic review of full economic evaluations. Nephrology. 2014; 19: 459-470 doi: 10.1111/nep.12269.
[289] Walker R, Howard K, Morton R. Home hemodialysis: A comprehensive review of patient-centered and economic considerations. ClinicoEconomics and Outcomes Research. 2017; 9: 149-161.
[290] Howard K, Salkeld G, White S, McDonald S, Chadban S, Craig J, Cass A. The cost effectiveness of increasing kidney transplantation and home-based dialysis. Nephrology. 2009; 14: 123-132 doi: 10.1111/j.1440-1797.2008.01073.x.
[291] Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verreli M, Oliver M. Impact of Modality Choice on Rates of Hospitalization in Patients Eligible for Both Peritoneal Dialysis and Hemodialysis. Peritoneal Dialysis International. 2014; 34(1): 41-48 doi: 10.3447/pdi.2012.00257.
[292] Sinnakirouchenan R, Holley, J. Peritoneal Dialysis Versus Hemodialysis: Risks, Benefits, and Access Issues. Advances in Chronic Kidney Disease. 2011; 18(6): 428-432. doi: 10.1053/j.ackd.2011.09.001.
[293] Rivara MB, Mehrotra R. The Changing Landscape of Home Dialysis in the United States. Current Opinion in Nephrology and Hypertension.2014; 23(6):586-591.doi:10.1097/MNH0000000000000066.
[294] Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar Outcomes With Hemodialysis and Peritoneal Dialysis in Patients With End-Stage Renal Disease. Archives of Internal Medicine. 2011; 171(2): 110-118. Doi:10.1001/archinternmed.2010.352.
[295] Ghaffarri A, Kalantar-Zadeh K, Lee J, Maddux F, Moran J, Nissenson A. PD First: Peritoneal Dialysis as the Default Transition to Dialysis Therapy. Seminars in Dialysis. 2013; 26(6): 706-713. doi: 10.1111/sdi.12125.
[296] Ledebo I, Ronco C. The best dialysis therapy? Results from an international survey among nephrology professionals. Nephrology Dialysis Transplantation.2008;6:403-408.doi:10.1093/ndtplus/sfn148.
[297] Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrology News & Issues. September 2010; 36-44.
[298] United States Renal Data System, 2018 Annual Data Report. Available at *https://www.usrds.org/2018/view/v2_01.aspx*.

receive dialysis at home. We also sought comments on how to support more equitable access to home dialysis across different ESRD patient populations.

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters expressed strong support for our efforts to support home dialysis through the ESRD QIP, noting that home dialysis can be medically effective and provide a potentially higher quality of life for ESRD patients and that monitoring the quality of care for home dialysis patients will have a meaningful impact on increasing utilization of home dialysis.

Several commenters recommended CMS develop a home dialysis patient experience of care survey that would capture feedback from patients on home dialysis. A few commenters noted the importance of a quality-of-life measure that accounts for the unique issues that are associated with dialyzing at home. One commenter recommended that CMS develop a new instrument to develop a patient experience survey which would include questions that specifically measure patient experience of home dialysis care, including components of in-center dialysis, patient training on home medical equipment, supplies, and safety, as well as communication with and access to health care providers. One commenter noted that any potential survey should be rigorously tested to ensure validity and reliability. One commenter further recommended that as a preliminary step, CMS could report a measure of Activities of Daily Living, which is closely linked to quality of life.

A few commenters observed the importance of comparing home dialysis patient experiences to in-center patient experiences because measuring home dialysis patient experiences and comparing those experiences to those of in-center patients will become increasingly important as the home dialysis patient population grows, and as results and familiarity with the survey tool are gained. One commenter recommended that CMS pursue and incorporate patient-reported home dialysis experiences into a QIP measure because measuring patients' experiences and being able to compare those experiences to those of in-center patients

will become increasingly important and because tracking retention on home dialysis including transferring from one home modality to another is critical to understanding shifts in home dialysis care. One commenter recommended that CMS use distinct hemodialysis and peritoneal dialysis adequacy measures endorsed by the NQF so that patients, caregivers, and care providers can access performance on specific dialysis modality types to make informed decisions about modality choice.

Several commenters supported a home dialysis rate measure, which commenters believe will help encourage facilities to place patients suitable for home dialysis on this modality. A few commenters recommended that CMS adopt a home dialysis retention rate measure (excluding transplant and mortality) to ensure that facilities are incentivized to support home dialysis patients and proactively address barriers such as patient comfort with dialysis technology and supply management.

Several commenters supported a home dialysis retention measure because it is important to maintaining existing home patients on home therapy. A few commenters stated that home dialysis patient retention measures are helpful quality indicators and can help facilities identify how to better support their home dialysis patients. One commenter recommended that CMS capture home dialysis retention by modality because this focus would create improvement in addressing transition management, which is a significant challenge to home dialysis utilization. This commenter recommended that CMS consider transition to in-center HD, transplant, and mortality as the three components of measuring home dialysis retention by modality. A few commenters recommended a retention measure that could help assess the quality of home training and help incentivize facilities to take steps to manage patient and care partner burnout. One commenter recommended CMS include routine assessment of family caregivers involved in dialysis patients' care as a quality indicator. One commenter recommended that CMS should measure home dialysis retention and home patients' experiences in the ESRD QIP because a

critical measure of success for home dialysis is avoiding "drop-out" or permanent conversion to in-center dialysis.

A few commenters recommended that CMS adopt the home dialysis rate and home dialysis retention measures developed by the Kidney Care Quality Alliance (KCQA). One commenter expressed caution that the current health care system is not adequately prepared for an influx in home dialysis treatment, which may lead to negative patient impacts and technique failure rates. This commenter stated that the home dialysis rate and retention measures have been developed to promote steady growth in home dialysis uptake and retention to minimize potential unintended or adverse consequences that may occur with unchecked, rapid growth in home dialysis without proper monitoring and assessment of the quality of care. One commenter requested that CMS examine home dialysis retention through adopting measures such as CMS's Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR). This commenter recommended that these measures exclude facilities with fewer than 11 eligible patients to ensure an adequate sample size.

A few commenters recommended that CMS adopt the Home Dialysis Care Experience instrument as a patient-reported experience of care measure to measure home dialysis patient experience. One commenter recommended a measure of home dialysis patient satisfaction, but expressed concern that the Home Dialysis Care Experience measure does not capture outcomes or the patient experience.

A few commenters recommended that CMS further explore the role of telehealth in providing care to home dialysis patients, noting that telehealth and in-home training may help support prospective home dialysis patients who may not have reliable access to transportation. A few commenters recommended that CMS consider the benefits associated with remote monitoring, including patient engagement and outcomes, as well as caregiver experience. One commenter also recommended that quality indicators for home dialysis should account for the

benefits of ongoing remote monitoring and its enablement of real-time trending and interventions.

A few commenters observed that lower levels of health literacy are barriers to equitable access to home dialysis. A few commenters recommended that CMS consider efforts aimed at timely CKD screening and education for patients, particularly those in communities of color, to promote more equitable access to home dialysis across different patient populations. A few commenters recommended that CMS establish standard requirements for care providers to discuss dialysis modality options with patients early on, preferably prior to beginning dialysis, so that patients have sufficient time and resources to make an informed decision about their treatment options. A few commenters recommended that the KDE benefit be expanded to allow more patients to access KDE services and permit more providers to provide the services. One commenter suggested that such services could be provided through telehealth platforms, and encouraged the passage of "The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021" to further such efforts. One commenter recommended including kidney disease screening in the "Welcome to Medicare" preventive visit as it would help with early detection of CKD and allow patients and providers to slow progression and discuss treatment modalities.

Several commenters noted that many barriers exist to equitable access to home dialysis, including social determinants of health-related challenges such as lack of support, space, transportation, and access to facilities providing home dialysis as an option. A few commenters made suggestions aimed at supporting home dialysis patients so they feel comfortable with the process of doing dialysis at home. One commenter recommended that patients should be trained to do their own home dialysis treatments in an in-center setting before going home so that they feel comfortable with that additional responsibility and can be more self-sufficient, which would also reduce the burden on dialysis staff. One commenter recommended that CMS stipulate specific guidance in providing clinician support to patients during their first year of home

dialysis because that support is critical to the overall success of the home dialyzer. One commenter recommended that CMS bring back staff-assisted home dialysis with clear parameters and guidelines because it has been shown to achieve higher rates of home dialysis and has the highest rate of retention.

A few commenters stated that financial barriers exist to equitable access to home dialysis, including the inability to afford costs associated with home dialysis. A few commenters recommended that, to address barriers to health equity and broaden access to home dialysis, CMS offer payment options for modifications a patient may need to make to their home environment to support home dialysis care. A few commenters also suggested that CMS remove financial barriers to home dialysis, such as eliminating copays for home dialysis training or exploring opportunities to provide financial support for staff-assisted home dialysis. One commenter recommended that CMS work with community and patient advocates to address financial concerns faced by patients so that patients understand their rights. One commenter noted the financial burden associated with home dialysis, such as increased water bills due to the use of a reverse osmosis machine, and the need for additional supplies to handle associated medical waste.

A few commenters noted that, to address existing barriers to equitable access to home dialysis, the government must expand access to CKD screening, incentivize specialization in nephrology, treat and educate patients on CKD earlier on, and address a patient's specific concerns regarding home dialysis that may impact a patient's decision-making. One commenter recommended that CMS provide coverage for nurse or caregiver services to support home dialysis patients. One commenter requested that CMS allow more flexibility in Medicare program rules to enable providers to work more closely with patients to overcome barriers to home dialysis, many of which result from factors related to social determinants of health.

One commenter recommended that home dialysis quality measures should include stratification by race and ethnicity to ensure home dialysis is being offered equitably. One

commenter recommended that CMS add a measure to determine equal access to home dialysis that includes patient demographics and reason(s) why the patient did not choose a home dialysis option or was not suitable because USRDS data show Black and Hispanic patients are vastly underrepresented among those on home dialysis and without more data it is impossible to know and address why this occurs.

A few commenters suggested that CMS broaden the applicability of current ESRD QIP measures to include home dialysis patients, noting that home dialysis is underrepresented in the current ESRD QIP measure set. A few commenters recommended a measure that surveils bloodstream infection in home hemodialysis patients. One commenter recommended revising the ICH CAHPS to include home dialysis. One commenter recommended CMS consider a Technical Expert Panel (TEP) to determine the most appropriate survey questions and prioritize either new development of a measure or validation and refinement of existing tools to capture the experiences of patients receiving home-based dialysis, noting that the current ICH CAHPS survey focuses on HD, whereas most home dialysis patients are on PD. One commenter recommended expanding the Kt/V Dialysis Adequacy measure. One commenter recommended prioritization of outcome measures that focus on relevant outcomes such as reporting peritonitis rate, inpatient readmission rates, and mortality. One commenter recommended that CMS explore hospitalization as an indicator of quality care for home dialysis patients, noting that the hospitalization rate is the biggest factor in reducing the total cost of care for home dialysis. One commenter recommended that CMS tailor measure performance standards within the ESRD QIP separately for in-center dialysis and home dialysis. This commenter also recommended that performance on a dialysis adequacy measure could be assessed separately within modality and then reaggregated at the facility level, which commenter believes would maintain a comprehensive dialysis adequacy measure while further promoting the uptake of home dialysis.

A few commenters expressed concern with our efforts to expand the ESRD QIP to include more home dialysis measures. One commenter expressed concern that scoring home

dialysis programs on only a few measures is a barrier to home dialysis uptake due to the risk for an ESRD QIP payment reduction. One commenter noted that home dialysis programs are negatively impacted by current ESRD QIP scoring and recommended that CMS revise the scoring methodology for home dialysis programs, to reweight measures, establish appropriate benchmarks, and create reporting minimums for the home dialysis programs. Although the commenter expressed support for additional opportunities to monitor the quality of care for home dialysis patients, the commenter did not support the inclusion of additional measures aimed at home dialysis in the ESRD QIP. This commenter recommended that if any home dialysis measure is included in the ESRD QIP, that such measure be a reporting measure and exclude nursing home patients due to unique nature of their care needs. One commenter did not support the RFIs on ESRD QIP because they believe there is inadequate adjustment for or inclusion or pediatric patients within the RFI which results in financial penalization exacerbating inequities in provision of ESRD care to pediatric patients.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of our efforts to support home dialysis. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our home dialysis-related efforts.

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 health care 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 health care, are significant risk factors associated with worse health outcomes as well as increased health care utilization.[299] In the CY 2023 ESRD PPS proposed rule, we stated our belief that consistently pursuing identification of HRSNs would have two significant benefits (87 FR 38554). 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.[300] 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.

In the proposed rule, we stated that we are investigating potential integration of screening for health-related social needs into the ESRD QIP measure set (87 FR 38554). This type of screening was the subject of the recently ended Accountable Health Communities (AHC) Model, which was implemented by the CMS Innovation Center.[301] The CMS 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.[302] HRSNs are significant risk factors associated with adverse health outcomes and increased health care utilization, including

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[299] 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.
[300] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed:
January 18, 2022. Available at: https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.
[301] Additional information about the Accountable Health Communities Model is available at: https://innovation.cms.gov/innovation-models/ahcm
[302] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.

excessive emergency department (ED) visits and avoidable hospitalizations.[303,304] 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.[305,306,307]

We stated our belief that 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 health care outcomes, including hospital readmissions, that result in higher penalties related to diminished quality performance.[308,309] We stated our belief that these measures align with *The CMS Quality Strategy Goals* around effective care coordination and prevention and treatment of chronic

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[303] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: https://doi.org/10.31478/201705b.

[304] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: https://doi.org/10.1056/NEJMp1512532.

[305] 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.

[306] 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.

[307] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203-212, doi: 10.3945/an.112.003277.

[308] 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.

[309] 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.

conditions.[310] We noted 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.[311] In the proposed rule, we sought 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.[312,313] The COVID-19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and health care utilization in the United States.[314,315] 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.[316,317,318,319] Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a

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[310] 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

[311] 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.

[312] 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.

[313] 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.

[314] 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.

[315] 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.

[316] 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.

[317] 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/.

[318] 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.

[319] 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.

nephrologist before starting dialysis.[320] 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.[321] Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and health care utilization and costs.[322,323,324,325] 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.[326,327]

In the proposed rule, we stated our belief that 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 health care providers. Recognizing the importance of social drivers of health, this year we have finalized proposals to include social drivers of health screening measures in the Hospital Inpatient Quality Reporting Program (87 FR 49202 through 49220). In the CY 2023 ESRD PPS proposed rule, we stated our belief that screening for social drivers of health would similarly help inform facilities and other health care providers of the impact of HRSNs in people with ESRD, including their health outcomes and health care utilization (87 FR 38555). The Screening for Social Drivers of Health 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

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[320] 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

[321] CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.

[322] 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.

[323] Dean, E.B., French, M.T., Mortensen, K. (2020). Health Services Research 55 (Supplement 2): 883-893. doi: 10.1111/1475-6773.13283.

[324] 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.

[325] 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.

[326] *Ibid.*

[327] 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.

needs, utility difficulties, and interpersonal safety.

In the CY 2023 ESRD PPS proposed rule, we stated that CMS's 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. In the proposed rule, we noted that we are exploring potential future inclusion of social drivers of health screening measures to the ESRD QIP. Therefore, we sought public comment on adding a new measure, Screening for Social Drivers of Health, to the ESRD QIP measure set in the next rulemaking cycle. We stated that 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.

In the proposed rule, we stated our belief that 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.[328,329] We stated our belief that 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 noted our belief that publishing social drivers of health screening rates would be helpful to many patients who need additional care coordination but may experience

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[328] *Ibid.*

[329] 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.

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

In the CY 2023 ESRD PPS proposed rule, we stated our belief that it is important to screen patients with ESRD for HRSNs that can negatively impact health outcomes and contribute to avoidable hospitalizations (87 FR 38556). 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.[330,331] 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.[332] Housing instability and transportation difficulties both contribute to interruptions in dialysis care which leads to avoidable hospitalizations.[333,334] Additionally, the COVID-19 pandemic has highlighted associations between disproportionate health risk, hospitalization, and adverse health outcomes.[335, 336] Capturing HRSN data may facilitate strengthening of linkages between

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[330] 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/.

[331] 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.

[332] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203-212, doi: 10.3945/an.112.003277.

[333] 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.

[334] 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.

[335] 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.

[336] 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.

facilities, medical providers (inpatient and outpatient), and community-based organizations which potentially could enhance care coordination for this group. Therefore, we sought 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. In the CY 2023 ESRD PPS proposed rule, we also stated our belief 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 (87 FR 38556). 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 welcomed public comment on potentially adding these two related Social Drivers of Health measures to the ESRD QIP measure set. We also welcomed public comment on data collection, submission, and reporting for these two measures. We received comments in response to this request for information and have summarized them here. We also note that since publication of the CY 2023 ESRD PPS proposed rule, we finalized the adoption of these two measures for the Hospital Inpatient Quality Reporting Program (87 FR 49201 through 49220).

Comment: Many commenters supported addition of the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures to the ESRD QIP measure set as part of future rulemaking efforts. Commenters supported these two measures as important steps towards meaningful measurement of unique challenges affecting dialysis patients and their health outcomes. Commenters believed the two measures will align well with CMS' commitment to health equity because they will enable identification of health disparities in dialysis patients. Additionally, commenters believed the measures will clarify understanding of

the overall impact of HRSNs in dialysis patients at the facility level by capturing relevant data for diverse patient cohorts. Several commenters highlighted the potential for these measures to inform actionable planning at the facility level and for resource allocation with the ESRD QIP. A few commenters noted the measures will improve understanding of access to appropriate care continuity for patients from under-resourced communities and consequently, provide evidence of health disparities in the management of specific disease and associated outcomes that disproportionately affect these groups. One commenter noted that dialysis providers are in a unique position because they see most of their patients three times per week and often form trusting relationships, which provide opportunities for screening for social drivers of health. One commenter cited opportunities to promote whole-person care, particularly in CKD and ESRD patients from communities that have been underserved and/or historically marginalized by the health care system, as the rationale for their support for adding the two Social Drivers of Health measures to the ESRD QIP measure set.

Several commenters provided specific and related reasons for supporting the two Social Drivers of Health measures, including valuable data capture of HRSNs affecting dialysis patients which they believe would inform quality improvement strategies to help advance health equity. One commenter noted the two measures could help inform actionable planning at the facility level and overall resource allocation within the ESRD QIP. Another commenter believes the measures will improve understanding of access to appropriate care continuity for dialysis patients from communities that are under-resourced and allow evaluation of health disparities in the management of specific diseases that disproportionately impact patient outcomes in this population.

Several commenters expressed support for the addition of the two Social Drivers of Health measures to the ESRD QIP measure set and offered specific recommendations for their implementation. A few commenters recommended CMS consider the use of Z codes to document patients' HRSNs, with a focus on the most common non-clinical barriers to home

dialysis, including housing instability, financial insecurity, inadequate caregiver support, and advanced age. A few commenters recommended CMS address how the measures will be implemented, specifically how the Social Drivers of Health data would be used to link patients to follow-on community-based services to address HRSNs. One commenter recommended the measures be classified as reporting measures, not performance measures, while another recommended voluntary reporting for the measures with patients being able to opt-out to prevent penalization for patients who refuse to participate in Social Drivers of Health screening. A commenter recommended CMS consider a trial period to test the feasibility of Social Drivers of Health screening process in dialysis patients. One commenter recommended CMS submit the two Social Drivers of Health measures for NQF review and approval prior to adding them to the ESRD QIP measure set. A commenter recommended screening be comprehensive to include the needs of family caregivers, since caregiver burden can prompt an emergency department visit or hospitalization. One commenter noted the important role that social workers in dialysis facilities can play in assessing HRSNs and connecting patients to available resources. A commenter recommended selection of The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) developed by the National Association of Community Health Centers, Inc (NACHC) as the screening instrument for the HRSN screening measure because it will address the five core HRSN domains noted in the RFI. One commenter recommended CMS consider how pediatric ESRD patients are impacted by issues such as housing instability, food insecurity, and transportation needs. A commenter recommended that CMS require dialysis facilities to report Social Drivers of Health data in EQRS and encourage them to address patient-level HRSNs in individual care planning and at the facility-level in Quality Assessment and Performance Improvement meetings.

A few commenters expressed support for the addition of the two Social Drivers of Health measures to the ESRD QIP measure set but expressed concerns about their implementation. A few commenters expressed concerns about the limited availability of community-based resources

to address dialysis patients' HRSNs. A few commenters did not believe that quality measurement is the appropriate approach for addressing patients' social needs. A few commenters expressed concern about documentation burden for providers and patients if the screening tool would be self-administered.

Several commenters expressed concerns and noted questions related to the actual screening process for the Social Drivers of Health measures. A few commenters were specifically concerned about potential use of the Accountable Health Communities Model (AHC) Screening Tool for capturing Social Drivers of Health data in the ESRD QIP. One commenter noted the tool has not been reviewed by NQF for appropriate utilization in a penalty-based accountability program. Another commenter noted the AHC Model Screening Tool has not been validated in ESRD patients. One commenter recommended use of The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) developed by the National Association of Community Health Centers, Inc (NACHC) as the instrument for Social Drivers of Health screening in the ESRD QIP because it is national standardized patient risk assessment protocol designed to engage patients in assessing and addressing social drivers of health because it is paired with an Implementation and Action Toolkit, and standardized across ICD-10, LOINC, and SNOMED. A commenter recommended CMS consider a focused question set to eliminate the need for annual screening. One commenter recommended testing the AHC Screening Tool for feasibility, accuracy, and validity before introducing it to existing data collection requirements for the ESRD QIP.

Several commenters supported the Screening for Social Drivers of Health measure in particular, noting the ability of that measure to capture HRSN data that inhibits dialysis patients' ability to access and participate in appropriate care and treatment, and increased availability of essential data to support health care professionals, including registered dietitian nutritionists and community and social services providers. One commenter recommended CMS provide guidance on addressing ERSD patients' HRSNs. A commenter recommended CMS establish universal

standards for screening to address timeframe, data collection and use. A commenter recommended an incremental approach to adding the Screening for Social Drivers of Health measure to the ESRD QIP measure set to start with voluntary reporting on one HRSN with subsequent introduction of additional domains over time and mandatory reporting to start the second year because it would allow dialysis facilities to become more familiar with HRSNs and screening process logistics.

One commenter specifically supported the Screen Positive Rate for Social Drivers of Health measure because it believes the measure is the next logical step after screening for drivers of health. Another commenter agreed that the measure has the potential to enable development of action plans to address the HRSNs for which dialysis facilities would screen.

A few commenters expressed concerns about adding the Screen Positive Rate for Social Drivers of Health measure to the ESRD QIP measure set. One commenter was concerned about potential penalization for facilities providing care for more patients from communities that are historically underserved. Another commenter stated it is essential that a higher screen positive rate is not used to reduce quality standards or expected outcomes for a given facility. One commenter expressed similar concerns about availability of the measure specification similar to the Screening for Social Drivers of Health measure and asked that CMS provide additional information on screening requirements in the context of the ESRD QIP.

A few commenters provided recommendations for implementing the Screen Positive Rate for Social Drivers of Health measure. One commenter recommended that CMS provide requirements for action plans to address HRSNs when patients screen positive, either within the measure itself or through patient follow-up requirements, to make the measure meaningful to patients. A commenter suggested that CMS eventually require referrals that link patients to services to address their HRSNs after screening. One commenter recommended that CMS consider other opportunities to leverage existing data sources to capture HRSN data.

Response: We thank the commenters for their feedback. We agree that screening for social drivers of health has potential to support meaningful measurement of unique challenges affecting dialysis patients and their health outcomes. We anticipate that such screening will align well with CMS's commitment to health equity because the measures will clarify understanding of the overall impact of HRSNs in dialysis patients. We also acknowledge the potential implementation issues and appreciate commenters' suggestions for mitigation strategies. We are committed to collecting and reporting data – including related to drivers of health – that will be relevant to the unique challenges facing the ESRD QIP patient population, and will take commenters' feedback into consideration in future policy development.

3. Request for Information on Overarching Principles for Measuring Health Care Quality Disparities Across CMS Quality Programs

a. Background

Significant and persistent inequities in health care 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.[337,338,339,340,341,342,343,344,345] In the CY 2023 ESRD PPS proposed rule, we stated that we are committed to achieving equity in health care outcomes for our beneficiaries by supporting health care providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting health care provider accountability for health care disparities (87 FR 38556 through 38557).[346]

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."[347]

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[337] 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.

[338] 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.

[339] 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.

[340] 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.

[341] 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.

[342] 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.

[343] 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.

[344] 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.

[345] 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.

[346] 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.

[347] https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government

In the CY 2023 ESRD PPS proposed rule, we stated that 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 (87 FR 38557). We noted that 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.[348]

Such disparities in health outcomes and health care 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 health care, irrespective of individual characteristics, in the CY 2023 ESRD PPS proposed rule we stated that we are committed to supporting dialysis providers and health systems in building a culture of equity that focuses on educating and empowering the health care workforce to recognize and eliminate health disparities in ESRD patients (87 FR 38557).[349]

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

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[348] Centers for Medicare & Medicaid Services. (2022). Health Equity. Available at: https://www.cms.gov/pillar/health-equity.

[349] 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.

social risk factors for people with ESRD (86 FR 61930). Advancing health equity would require a variety of efforts across the health care system. The reduction in health care 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 health care disparities, including: the CMS Mapping Medicare Disparities Tool[350] and the CMS Disparity Methods stratified reporting.[351] 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);[352] 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.[353,354,355]

Measuring health care disparities and reporting these results to health care providers is a cornerstone of our approach to advancing health 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 health care disparities through stratification is only one method for using health care quality measurement to address health equity, but it is an important approach that allows health care

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[350] 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.
[351] Centers for Medicare and Medicaid Services. Disparity Methods Confidential Reporting. Available at: https://qualitynet.cms.gov/inpatient/measures/disparity-methods.
[352] https://www.federalregister.gov/documents/2013/09/24/2013-23164/national-standards-for-culturally-and-linguistically-appropriate-services-clas-in-health-and-health
[353] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Model. Available at: https://innovation.cms.gov/innovation-models/ahcm.
[354] https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.
[355] 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.

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.[356,357] 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 health care 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 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 health care system, and examining disparities across additional health care 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 feedback from interested parties 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

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[356] 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.

[357] 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.

foster the development of primary care practice teams to enhance care for medically underserved patients with CKD and are at risk of progression of disease or complications,[358] 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.[359]

In the CY 2023 ESRD PPS proposed rule, we noted that measuring health care 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 (87 FR 38558). 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.[360,361] 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, in the CY 2023 ESRD PPS proposed rule we stated our intent to continue to evaluate opportunities to expand these current measure stratification reporting initiatives with

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[358] 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.
[359] CMS (2021). ESRD Treatment Choices (ETC) Model. Available at: https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.
[360] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.
[361] http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.

existing sources of data (87 FR 38558). We noted that 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 stated that 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 feedback from interested parties 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 health care disparities and advance health equity. In the CY 2023 ESRD PPS proposed rule, we sought input on key considerations in five specific areas that could inform our approach (87 FR 38558). Each is described in more detail later in this section:

- *Identification of Goals and Approaches for Measuring Health Care Disparities and Using Measure Stratification in ESRD QIP* – This section identifies the approaches for measuring health care 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 health care disparity measurement. Dialysis and other health care 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 consider 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 then solicited public input on these topics.

b. Identification of Goals and Approaches for Measuring Health Care 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 health care disparities (that is, through quality measure stratification), we aim to provide useful tools for dialysis providers and facilities to drive improvements. In the CY 2023 ESRD PPS proposed rule, we stated our belief that 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 (87 FR 38558). 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 health care 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 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.[362] Second, a health care 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 health care 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.[363]

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

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[362] 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.

[363] 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.

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.

In the proposed rule, we stated that 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.[364] 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

In the proposed rule, we stated our intent to begin our efforts to provide stratified reporting for ESRD QIP measures, provided they offer meaningful and valid feedback to dialysis and other health care providers on their care for ESRD patients that may face social disadvantage or other forms of discrimination or bias (87 FR 38559). Further development of stratified reporting of ESRD QIP measures can provide dialysis and other health care providers with more granular results that support targeting resources and initiatives to improve health equity. We noted that 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 stated that we aim to receive feedback on several systematic principles under consideration that we believe would help us prioritize measures for disparity reporting across programs.

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[364] 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.

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.

In the CY 2023 ESRD PPS proposed rule, we noted that 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[365] 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 health care sector also aim to mitigate any potential additional administrative burden on health care providers, hospitals, and facilities.

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[365] Centers for Medicare and Medicaid Services. (2020). CMS Measures Management System Blueprint (Blueprint v 16.0).Available at: https://www.cms.gov/Medicare/Quality Initiatives-Patient-Assessment-Instruments/MMS/ Downloads/Blueprint.pdf.

- *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 health care 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 to demonstrate evidence of disparity in care for some or most health care 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 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.

In the proposed rule, we stated that 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 (87 FR 38560). Large differences in care for patients along social or demographic lines may indicate high potential that targeted initiatives could be effective. We noted that 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 health care disparities. Measures that address health care 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, we stated in the proposed rule that the ESRD QIP would consider prioritizing measures with a focus on access to or appropriateness of care (87 FR 38560). 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 health care 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.[366,367,368,369,370,371,372,373] 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."[374] 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.[375,376] 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.[377]

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

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[366] 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.
[367] 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.
[368] 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.
[369] 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.
[370] 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.

[371] 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.

[372] 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.

[373] 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.
[374] World Health Organization. Social Determinants of Health. Available at: https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.
[375] 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.
[376] 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.
[377] 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/.

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.[378] 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), in the proposed rule we stated our belief 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 (87 FR 38560). We noted that 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, in the proposed rule we stated that we are considering three sources of social risk and demographic data that would allow us to report stratified measure results:

- *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. In the proposed rule, we noted that 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

[378] 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.

analyses.[379] 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.[380] 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.[381,382] 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)

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[379] 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.
[380] 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.
[381] 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.
[382] 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.

Socioeconomic Status (SES) Index,[383] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Social Vulnerability Index (CDC/ATSDR SVI),[384] and Health Resources and Services Administration Area Deprivation Index,[385] 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.[386] 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

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[383] 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.

[384] 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.

[385] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: https://www.neighborhoodatlas.medicine.wisc.edu/.

[386] 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/.

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.[387]

While the use of area-based indicators and imputed data sources are not meant to replace efforts to improve patient-level data collection, in the proposed rule we noted that 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 interested parties for face validity, and any calculations that incorporate these 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.[388] Even more potent, when patient-level

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[387] 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/.

[388] 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.

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, in the proposed rule we stated that 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 noted our 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 stated that we looked 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 health care 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 health care 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 health care 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 interested parties 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. Interested parties have stated 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

In the proposed rule, we stated that there are several options for reporting of disparity results to drive improvements in quality (87 FR 38562). 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 health care 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 health care providers for having low disparity rates, or for performing well for medically underserved population groups.

We stated that we are exploring the most optimal methods of reporting disparity results. Initially, confidential reporting may be prudent for facilities and health care providers to understand stratification methodology and the presentation of stratified results, and to begin to implement programs to reduce disparities at their facilities. We noted that 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. In the proposed rule, 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. In the proposed rule, we stated our intent 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 health care 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

In the proposed rule, we stated that the goal of this request for information was to describe key considerations that we would acknowledge when advancing the use of measure stratification as one quality measurement tool to address health care disparities and advance health equity in the ESRD QIP. We also stated that this was important as a means of setting priorities and expectations for the use of stratified measures. We specifically noted that several important factors may limit the use of stratification or may need to be taken into consideration.

We invited 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 invited 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 sought 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.

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters supported efforts to address disparity measurement and health equity in the ESRD QIP. Several commenters specifically supported stratification as a potential approach to identifying the impact of health disparities in diverse population groups. One commenter stated that health disparities measurement will advance policies and practices that will promote health equity and improve health outcomes in patients from populations that are historically underserved. A few commenters noted that measure stratification will reveal the impact of social risk factors on health outcomes. One commenter identified the Percentage of Prevalent Patients Waitlisted (PPPW) measure as priority for stratification if the ESRD QIP measure set. A commenter stated that measure stratification by race, ethnicity, and dual eligibility status may be too broad to decipher the underlying cause of health disparities, but supports collection of this data as an important preliminary step. One commenter expressed general support for the creation of an ESRD Facility Equity Score and believes dialysis facilities should be accountable for closing health equity gaps with support and guidance from CMS. A commenter recommended that CMS work with interested parties to identify evidence-based measurable solutions to addressing health disparities.

Several commenters expressed concerns about the implementation of health disparities measurement in the ESRD QIP. A few commenters identified the potential for increased administrative burden as a concern. A few commenters expressed concern about CMS's plans to ensure that valid data collection and subsequent analytic procedures are in place. One commenter was concerned that measure stratification could potentially increase financial penalties for facilities that serve patients experiencing poverty or another disadvantage. Another commenter noted that dialysis facilities may have difficulties with data collection due to resource limitations and patient preferences.

Commenters offered multiple recommendations for future measurement of health disparities in the ESRD QIP. A few commenters recommended that CMS consider potential administrative burden in development of data collection and reporting procedures. Another commenter recommended that CMS include specific health equity measures in the ESRD QIP measure set to ensure financial accountability for facilities. One commenter noted the disproportionate impact of ESRD on patients from communities that are historically under-resourced and recommended enhanced attention to CKD prevention, quality of life improvement for CKD and ESRD patients and increased access to home dialysis and transplantation as treatment modalities. A commenter noted the importance of fairly applying quality incentives to promote equitable access to high-quality care and recommended incorporation of social risk factors into future analytic methodologies. One commenter recommended that patients be able to opt-out of participation in health disparities data collection.

Many commenters noted that they would like to see health disparity measurement linked to actionable planning that will advance health equity, and several commenters provided multiple recommendations for measuring health disparities. A few commenters supported using "within-provider" and "across-provider" approaches. A few commenters requested that CMS work with interested parties to define performance methodologies and reporting requirements, specifically related to stratification of measures. These commenters were especially concerned that CMS

consider efforts to reduce administrative burden and financial penalization associated with serving patients from communities that are historically underserved while ensuring accurate and fair assessment performance evaluation at the facility level.

A few commenters recommended that CMS prioritize measures that have a sufficient sample size so that comparisons are reliable and representative. A few commenters suggested that CMS prioritize outcome measures and measures of access and appropriateness of care. A few commenters requested that CMS clarify the definition of access and appropriateness of care measures. One commenter recommended that CMS prioritize validated and reliable clinical quality measures over reporting measures. Another commenter recommended that CMS prioritize measures that are supported by evidence of disparities identified for selected social or demographic factors. One commenter recommended prioritization of measures that are directly related to patient outcomes, measures for which disparities are the largest, measures for which disparities are worsening, and measures that are actionable. One commenter recommended that CMS establish standards for stratification and robust segmentation to identify existing gaps in outcomes within patient groups. One commenter recommended initial prioritization of measures that facilities have experience with collecting and reporting to ensure that stratified measures have been validated and align with CMS priorities such as clinical quality, safety, and patient experience measures.

Several commenters recommended that CMS leverage existing data sources, including patient-level self-reported data, to stratify ESRD QIP measures by such factors as race and ethnicity, income, insurance status at the initiation of dialysis treatment and geographic area of residence. One commenter recommended that CMS develop and make available datasets that will track how closely the community generally, and each provider specifically, provides care across key demographic groups and whether that care aligns with the demographics of the service area. A few commenters noted the importance of collecting social drivers of health data for future resource allocation. A few commenters believed that z-code data would be a

meaningful approach to increasing understanding of the impact of demographic and social risk factors in ESRD patients. A few commenters recommended that CMS take a stepwise approach to stratification of ESRD QIP measures, suggesting stratification according to dual-eligibility status as an appropriate starting place. One commenter recommended that CMS account for physical disability and limited English proficiency as key variables because patients with these characteristics may generate greater costs to the healthcare system due to mobility restrictions and need for translators. One commenter recommended that CMS make stratified health disparities data publicly available so that interested parties can better assess the diverse needs of different patient populations.

Several commenters provided recommendations for applying risk adjustment methods to identification of meaningful differences in disparity results. One commenter noted that risk adjustment should not include patients' clinical conditions because differences due to these factors are excluded from quality performance comparison. A few commenters stated that risk should control for clinical conditions and basic demographic characteristics (age and sex), which are legitimate reasons for variation in outcomes since they are biologically based and would potentially quantify outcome differences related to non-biological and/or social factors like race, ethnicity, and poverty that contribute to health inequities. One commenter believed risk adjustment methodologies incorporate utilization and cost variables to identify facility-level factors that may contribute to differences in ESRD patient outcomes including program design, provider characteristics and biases in care delivery or other non-clinical social factors. One commenter recommended identifying meaningful performance differences beyond process measures with more attention given to data-driven improved patient outcomes, including potentially avoidable hospital admissions, complications, readmissions, ambulatory complications, and emergency department visits that are adjusted for clinical and social risk. This commenter believed that reporting disparity results should track appropriate utilization to permit benchmarking for clinically similar cohorts because this approach would elucidate actual

versus expected differences in utilization outcomes. One commenter recommended that CMS consider using the Social Deprivation Index (SDI) tool to ascertain a more granular perspective on social risk factors in the ESRD population to prevent masking of additional disparities apart from race and ethnicity. Another commenter emphasized that it will be important for CMS to work with experts to test proposed methods and identify best practices for data collection and stratification to avoid inadvertent quality measurement bias and exacerbation of existing health disparities. One commenter did not support the use of rank ordering or percentiles to identify differences in performance because such approaches can potentially mask the actual performance between top and bottom ranked facilities. One commenter believed that using statistical differences, thresholds, and benchmarking are more appropriate methods for identifying meaningful differences.

Several commenters recommended that CMS initially implement confidential facility-level reporting. A few commenters supported confidential reporting prior to public reporting. A few commenters noted that initial confidential reporting would allow time for evaluation of data collection and analytic methodologies which can reduce risk of misinterpretation of facility-level data and selection bias among patients. One commenter believed that de-identified aggregate reporting of disparity results may be helpful for sharing results beyond the facility level. A few commenters stated that publicly reporting disparity data in the future will promote transparency and accountability. One commenter cautioned against public reporting of disparity data because facilities have resource constraints that prohibit them from providing patients with social supports. Another commenter recommended that CMS collaborate with the kidney care community in future efforts to identify and address health disparities in ESRD patients.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of CMS health equity efforts. We will continue to take all concerns, comments, and suggestions into account for future policy development and expansion of our strategic vision for advancing health equity. For more

information on these ongoing efforts, we refer readers to our recently released CMS National Quality Strategy (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy), the CMS Strategic Plan for Health Equity (https://www.cms.gov/files/document/health-equity-fact-sheet.pdf), and the CMS Framework for Health Equity (https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/framework-for-health-equity) in which we describe our five priorities for advancing health equity.

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 the beneficiaries of these programs. 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.[389] 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.

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[389] ZIP code™ is a trademark of the United States Postal Service.

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).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the ETC Model

The CY 2023 ESRD PPS proposed rule appeared in the June 28, 2022 version of the **Federal Register**, with a comment period that ended on August 22, 2022. In that proposed rule, we proposed to make several changes to the ETC Model, effective January 1, 2023. We received 33 timely public comments on our proposals, including comments from ESRD facilities and dialysis organizations; national renal, nephrologist, and patient organizations; manufacturers; healthcare systems; and individual clinicians.

We also received comments related to issues that we did not discuss in the CY 2023 ESRD PPS proposed rule. These include, for example, general expressions of support for the ETC Model, the focus on increasing rates of home dialysis and transplantation, and the policies related to reducing disparities; recommendations for additional ways to refine the model, including changes to ETC Participant selection and ESRD Beneficiary attribution, aggregation group construction, and the achievement benchmarking methodology; concerns related to the

impact of COVID-19 and the COVID-19 PHE on the ETC Model and ETC Participants; and recommendations to make the ETC Model, or specific elements of the ETC Model, available nationally. While we are generally not addressing those comments in this final rule, we thank commenters for their input and may consider their recommendations in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ETC Model. These policies take effect January 1, 2023.

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 $<30^{th}$, $\geq 30^{th}$, $\geq 50^{th}$, $\geq 75^{th}$, and $\geq 90^{th}$ percentile of rates for Comparison Geographic Areas during the Benchmark Year. An ETC Participant receives the achievement points 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).

As discussed in the CY 2023 ESRD PPS proposed rule, based on subsequent analysis, we 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.

We explained that 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, in the CY 2023 ESRD PPS proposed rule, we proposed to further modify the achievement scoring methodology for the ETC Model. Specifically, we proposed 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 sought comment on this proposal.

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

Comment: Several commenters expressed support for our proposal to modify the achievement scoring methodology such that 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. One of these commenters stated that they agreed with our statement that awarding points for a home dialysis rate or a transplant rate of zero was counter to the intent of the model.

Response: We appreciate the commenters' support.

Comment: Several commenters stated that they appreciated CMS's continued efforts to refine the ETC Model regarding assessing ETC Participant achievement. Of these commenters, a few stated that they did not oppose this proposal, but suggested additional changes to assessing ETC Participant achievement, including changes to the achievement benchmarking methodology, such as weighting aggregation groups by size, increasing the number of strata, and basing achievement benchmarks on something other than rates observed in Comparison Geographic Areas during the Benchmark Year.

Response: We appreciate the commenters' continued engagement with the design of the ETC Model and the methodology by which we assess ETC Participant achievement. In the CY 2023 ESRD PPS proposed rule, we did not propose modifications to the achievement benchmarking methodology, and as such, we are not finalizing any changes to the achievement benchmarking methodology in this final rule. We may take these suggestions under consideration for potential future modifications to the ETC Model.

Final Rule Action: After considering the comments received, we are finalizing our proposal to add a requirement, by revising § 512.370(b) and adding § 512.370(b)(3), to specify that, for MY5 through MY10, 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.

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. In the CY 2023 ESRD PPS proposed rule, we proposed 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 proposed 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 also considered 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 recognized 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 did 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 finalized 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 solicited public comments on these proposed changes to § 512.397(b)(1). The comments on this proposal, and our responses to the comments, are set forth below

Comment: Several commenters supported our proposal to prohibit an ESRD facility or related entity from leasing or otherwise providing "clinical staff" for the purposes of furnishing kidney disease patient education services regardless of whether the ETC Participant reduces or waives the Beneficiary's coinsurance obligation. One commenter noted that the proposed 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 would protect patient choice. Another commenter agreed that beneficiaries should not be steered to any specific ESRD facility or chain of ESRD facilities.

Response: We appreciate the commenters' support.

Comment: Several commenters opposed our proposal to prohibit an ESRD facility or related entity from leasing or otherwise providing "clinical staff" for the purposes of furnishing kidney disease patient education services regardless of whether the ETC Participant reduces or waives the Beneficiary's coinsurance obligation. A few commenters opposed our proposal because they stated it could exacerbate the underutilization of kidney disease patient education services. One commenter stated that beneficiaries should have kidney disease patient education services furnished by the best qualified professionals, regardless of where they are employed. Several commenters who opposed our proposal stated that they would be willing to work with CMS to address issues with steering beneficiaries to a specific ESRD facility or chain of ESRD

facilities if they were to arise. Commenters also stated that CMS could create guardrails around steering beneficiaries to a specific ESRD facility or chain of ESRD facilities by producing non-branded materials for use in furnishing kidney disease patient education services.

Response: We appreciate the commenters' feedback. In the Specialty Care Models final rule, we waived certain Medicare payment requirements regarding kidney disease patient education services to give ETC Participants additional access to tools to educate beneficiaries about their renal replacement options (85 FR 61114). Educating patients about the management of comorbidities, prevention of complications, and therapeutic options and ensuring access to the best qualified health care professionals is essential to protecting Beneficiary choice. We agree that Beneficiaries should have access to the best qualified professionals, but we do not agree that the Beneficiary protections we are finalizing in this rule will preclude access to these professionals. We appreciate commenters' concerns that the inability to perform these services using staff leased from an ESRD facility or related entity could result in underutilization of kidney disease patient education services, but it is important that these services are furnished without any undue pressure on beneficiaries. While we appreciate commenters' willingness to work with CMS to address issues with steering that arise, we do not believe that we should finalize a policy that would simply result in remedial action if some patient education services were to result in patient steering. Because patient steering can be difficult for CMS to discover, we prefer to finalize a policy that would prevent the abuse from occurring in the first instance. Similarly, we do not believe that we have the resources to develop non-branded materials for use in furnishing kidney disease patient education services. We continue to believe that adding 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, is necessary to preserve patient choice regarding their treatment modality and the ESRD facility or chain of ESRD facilities from which they may receive treatment.

Comment: Several commenters expressed their support for further improving access to kidney disease patient education services. A few commenters recommended that CMS increase the types of qualified staff who would be permitted to provide kidney disease patient education services under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

Response: We thank commenters for their engagement with the waivers provided for the ETC Model test. We may take the recommendation to increase the types of qualified staff who would be permitted to provide kidney disease patient education services under consideration for potential future modifications to the ETC Model.

Final Rule Action: After considering the comments received, we are finalizing our proposal 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, only "clinical staff" that are not leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity may provide kidney disease patient education services. We believe this requirement is necessary to preserve patient choice of modality and ESRD facility or chain of ESRD facilities.

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 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, as discussed in the CY 2023 ESRD PPS proposed rule, 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. We explained that because 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 noted that we believed 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 sought 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. The comments and our responses are set forth below.

Comment: Several commenters supported our plan to publish de-identified ETC Model results on the ETC Model website.

Response: We appreciate the feedback from commenters and are planning to post the results on the ETC Model website at https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model, to promote transparency and to help educate the public about the effects of the ETC Model on beneficiaries.

Comment: We received requests for more details about what CMS will post, including requests for specific information about how publicly posted results will account for members of an aggregation group.

Response: CMS appreciates this feedback. As we described in the CY 2023 ESRD PPS proposed rule, we are only planning to post results at the aggregation group level, as well as a list of the relevant Managing Clinicians or ESRD facilities within the aggregation group. We plan to share results using a method similar to how we shared results with ETC Participants for each MY, which will give the overall payment adjustment and break down the individual components that go into the home dialysis rate and transplant rate, de-identified in accordance with 45 CFR 164.514(b).

Comment: We received multiple requests for the ability to pre-review results before they are posted publicly.

Response: CMS appreciates this feedback from commenters, but believes that the targeted review process outlined in 42 CFR 512.390(c) provides a sufficient opportunity for ETC Participants to review the results before they are posted publicly. As we described in the CY 2023 ESRD PPS proposed rule, we will post de-identified results at the aggregation group level, which will have already been reviewed by ETC Participants as part of the targeted review process.

Final Rule Action: CMS will publish performance data for Managing Clinicians and ESRD facilities after the conclusion of each Measurement Year. Consistent with the discussion

in the proposed rule, we will also publish results from MYs that have already been completed. We appreciate the feedback from commenters about how we should publish results and will represent results for aggregated performance groups in a clear manner.

VI. Collection of Information Requirements

We solicited 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. In the proposed rule, we stated that the most recently available median hourly wage of a Medical Records and Health Information Technician is $21.20 per hour (87 FR 38566).[390] In this final rule, we are updating the median hourly wage to $22.43 per hour, which reflects the most recently available data.[391] 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, in the proposed rule we estimated an hourly labor cost of $42.40 as the

[390] https://www.bls.gov/oes/2020/may/oes292098.htm.
[391] https://www.bls.gov/oes/current/oes292072.htm. Accessed on September 16, 2022.

basis of the wage estimates for all collections of information calculations in the ESRD QIP (87 FR 38566). In this final rule, we are updating our previously estimated hourly labor cost to $44.86 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 2023 ESRD PPS proposed rule (87 FR 38566) 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 final rule. Although we also proposed updates for PY 2023 and PY 2024, these proposals did 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 burden estimates associated with the PY 2023 or PY 2024 ESRD QIP due to our finalized policies in this final rule. Although we are finalizing the suppression of seven measures for PY 2023 instead of six measures as originally proposed, as discussed further in section IV.B.2 of this final rule, we believe that this will not impact the information collection burden, as facilities are still expected to continue to collect measure data during this time period for both suppressed and non-suppressed measures.

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 the proposed rule, we did not propose any changes to the EQRS data validation process. However, in this final rule, we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. 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 x 2.5 hours). Since we anticipate that Medical Records Specialists or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $33,645 (750 hours x $44.86), or an annual total of approximately $112.15 ($33,645/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will 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 the proposed rule, we did not propose any changes to the NHSN data validation process. However, in this final rule we are updating these burden estimates using a newly available wage estimate of a Medical Records Specialist. 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 x 5 hours). Since we anticipate that Medical Records Specialists or similar staff would submit these data, using the newly available wage estimate of a Medical Records Specialist, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $67,290 (1,500 hours × $44.86), or a total of approximately $224.30 ($67,290/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will 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 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 final rule, we are finalizing our six measure suppressions that would apply for PY 2023. We are also finalizing the suppression of the Standardized Fistula Rate clinical measure for PY 2023. However, we believe that finalizing these measure suppressions 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 for all ESRD QIP measures, including both suppressed and non-suppressed measures. 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 final 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 did not propose any changes in the 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 Specialists 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 the proposed rule we estimated that the amount of time required to submit measure data to EQRS was 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this final rule. There are 229 data elements for 514,406 patients across 7,847 facilities. At 2.5 minutes per element, this yields approximately 625.49 hours per facility. Therefore, the PY 2025 burden is 4,908,291 hours (625.49 hours x 7,847 facilities). Using the wage estimate of a Medical Records Specialist, we estimate that the PY 2025 total burden cost is approximately

$220 million (4,908,291 hours x $44.86). 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 final rule, we are finalizing our proposal to adopt a COVID-19 Vaccination Coverage among HCP 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.[392] 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).[393] Although the burden associated with the COVID-19 Vaccination Coverage among HCP 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.

We estimate that it would take each facility, on average, approximately 1 hour per month to collect data for the COVID-19 Vaccination Coverage among HCP 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[394] 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 70,623 hours (9

[392] More information on the NHSN can be found at: https://www.cdc.gov/nhsn/index.html.
[393] 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.
[394] https://www.bls.gov/oes/current/oes436013.htm (accessed on March 29, 2022). The adjusted hourly wage rate of $36.02/hour includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

hours/facility × 7,847 facilities) and 117,705 hours (15 hours/facility × 7,847 facilities) for all facilities. Each facility would incur an estimated cost of between $324.18 (9 hours × $36.02/hour) and $540.30 annually (15 hours × $36.02/hour). The estimated cost across all facilities would be between $2,543,840.46 ($324.18/facility × 7,847 facilities) and $4,239,734.10 ($540.30/facility × 7,847 facilities) annually. We recognize that many health care facilities are also reporting other COVID-19 data to HHS. We believe the benefits of reporting data on the COVID-19 Vaccination Coverage among HCP 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 did not receive any comments on the ESRD QIP collection of information discussions.

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 final rule provides updates and policy changes to the CY 2023 ESRD wage index values, the wage index budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish

this final rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to ESRD beneficiaries.

This rule also has a number of policy changes to improve payment stability and adequacy under the ESRD PPS. As discussed in section II.B.1.a.(1) of this final rule, we are finalizing our proposal to rebase and revise the ESRDB market basket to reflect a CY 2020 base year. We are also finalizing our proposals to increase the ESRD PPS wage index floor as discussed in section II.B.1.b.(3) of this final 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 final rule. Lastly, as discussed in section II.B.1.c.(4) of this final rule, we are finalizing our proposal to change our methodology for calculating the FDL amount for adults to target more effectively ESRD PPS outlier payments that equal 1 percent of total ESRD PPS payments. We believe that each of these changes will improve payment stability and adequacy under the ESRD PPS.

Furthermore, as discussed in section II.B.1.f. of this final rule, we are finalizing our proposal 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 change will improve beneficiaries' access to renal dialysis drugs, promote health equity, and advance other goals as discussed in that section of this final rule. Lastly, we are finalizing our proposal 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 clarification will improve public understanding of the ESRD PPS functional categories and drug designation process.

2. AKI

This final rule updates the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B.2 of this final rule, we are also finalizing our proposal 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 will apply under the ESRD PPS. We believe that these changes will improve payment stability and adequacy for AKI dialysis in ESRD facilities. Failure to publish this final 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 final rule finalizes updates for the ESRD QIP, including the suppression of several ESRD QIP measures for PY 2023 under our previously finalized measure suppression policy, an update to the PY 2023 performance standards, updates regarding the SHR clinical measure and the SRR clinical measure for PY 2024, and updates regarding the STrR and Hypercalcemia measures, the adoption of the COVID-19 Vaccination Coverage among HCP reporting measure, as well as a policy to create a new reporting measure domain and to re-weight measure domains, beginning in PY 2025.

4. ETC Model

We believe it is necessary to make certain changes to the ETC Model. ETC Participants will continue to receive adjusted payments but beginning MY5, certain aspects of the ETC Model used to determine those payment adjustments will change. The change to the PPA achievement scoring methodology is necessary to increase fairness and accuracy of the PPA. The 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, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these regulations, and the

Departments have provided an assessment of their impact in the following sections of this CY 2023 ESRD PPS final rule.

We solicited comments on the regulatory impact analysis provided in the CY 2023 ESRD PPS proposed rule.

Comment: Several individual commenters raised concerns that payment impacts for certain ESRD facilities, particularly several rural facilities, would be lower than the overall impact analysis presented in the proposed rule.

Response: As we noted in the CY 2023 ESRD PPS proposed rule (87 FR 38568), proposed updates to the wage index would have distributive impacts and would affect different ESRD facilities in different ways. We always strive to present as much information as possible in the proposed rule so that the costs and benefits of rulemaking can be effectively analyzed. In addition, we provide a facility-level impact file as an addendum to present impacts at a more granular level than can be presented in the **Federal Register**.

Final Decision: After consideration of the comments, we are finalizing our proposed methodology for analyzing the impacts of rulemaking. We have revised our impact analysis to reflect more recent data sources and information for this final rulemaking.

C. Impact Analysis

1. ESRD PPS

We estimate that the revisions to the ESRD PPS will result in an increase of approximately $300 million in payments to ESRD facilities in CY 2023, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and continuation of the approved TPNIES and TDAPA from CY 2022.

2. AKI

We estimate that the updates to the AKI payment rate will result in an increase of approximately $2 million in payments to ESRD facilities in CY 2023.

3. ESRD QIP

We estimate that the finalized updates to the ESRD QIP will result in an additional $32 million in estimated payment reductions across all facilities for PY 2025.

4. ETC Model

We estimate that the finalized changes to the ETC Model will not impact the Model's projected direct savings from payment adjustments alone. We estimate that the Model will 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 in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the CY 2023 ESRD PPS and AKI payment, ESRD facilities will 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 will enhance the efficiency of the Medicare program. Additionally, we expect that updating ESRD PPS and AKI payments by 3.0 percent based on the CY 2023 ESRD PPS market basket update less the CY 2023 productivity adjustment will 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 final rule regarding ESRD PPS and AKI rates-setting will create additional cost or burden to ESRD facilities.

b. ESRD QIP

As discussed in section IV.B.2 of this final rule, we are adopting measure suppressions that would apply for PY 2023. However, we believe that none of the policies that we are

finalizing in this final 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 Specialists 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.

We also finalized the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $220 million in information collection burden, which includes the cost of complying with this rule, and an additional $32 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 finalized in this final rule.

For PY 2026, we estimate that the finalized revisions to the ESRD QIP would result in $220 million in information collection burden, and $32 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 finalized in this final rule.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rate will result in a total in increase of approximately $300 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 updates to the AKI payment rate, of which approximately

20 percent is increased beneficiary co-insurance payments. We estimate approximately $240 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 final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We did not receive any public comments specific to our solicitation.

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

We sought public comments on this assumption. We did not receive any public comments specific to our solicitation.

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 will take approximately 316 minutes (5.3 hours) for the staff to review half of this final rule, which is approximately 79,000 words. For each entity that reviews

the rule, the estimated cost is $610.67 (5.2 hours x $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $177,704.97 ($610.67 x 291).

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 final rule, we used CY 2021 data from the Part A and Part B Common Working Files as of July 30, 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 updates to the ESRD PPS base rate are described in section II.B.1.d of this final rule. Table 31 shows the impact of the estimated CY 2023 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2022.

TABLE 31: Impacts of the Changes in Payments to ESRD Facilities for CY 2023[1]

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Changes to Outlier Policy (C)	Change to LRS (D)	Wage Index Changes (E)	Total Percent Change[2] (F)
All Facilities	7,882	35.5	0.0%	0.0%	0.0%	3.1%
Type						
Freestanding	7,506	34.1	0.0%	0.0%	0.0%	3.0%
Hospital based	376	1.4	0.1%	0.0%	0.0%	3.1%
Ownership Type						
Large dialysis organization	6,109	27.9	0.0%	0.0%	0.0%	3.0%

Regional chain	902	4.2	0.0%	0.2%	0.1%	3.4%
Independent	474	2.0	0.0%	0.3%	-0.1%	3.2%
Hospital based	376	1.4	0.1%	0.0%	0.0%	3.1%
Unknown	21	0.0	0.0%	0.1%	0.3%	3.4%
Geographic Location						
Rural	1,286	5.1	0.0%	-0.6%	-0.2%	2.3%
Urban	6,596	30.4	0.0%	0.1%	0.0%	3.2%
Census Region						
East North Central	1,224	4.8	0.0%	-0.2%	-0.4%	2.5%
East South Central	622	2.4	0.0%	-0.7%	-0.3%	2.0%
Middle Atlantic	895	4.4	0.1%	0.3%	0.0%	3.3%
Mountain	439	1.9	0.0%	-0.1%	-0.1%	2.9%
New England	202	1.2	0.0%	0.2%	-0.6%	2.7%
Pacific[3]	972	5.7	0.0%	0.8%	0.6%	4.5%
Puerto Rico and Virgin Islands	52	0.2	0.0%	-1.9%	7.1%	8.2%
South Atlantic	1,832	8.1	0.1%	-0.3%	-0.2%	2.5%
West North Central	517	2.0	0.1%	-0.3%	-0.3%	2.5%
West South Central	1,127	4.9	0.0%	-0.4%	0.3%	2.9%
Facility Size						
Less than 4,000 treatments	1,310	1.7	0.0%	-0.2%	-0.2%	2.6%
4,000 to 9,999 treatments	3,375	11.3	0.0%	-0.2%	-0.1%	2.7%
10,000 or more treatments	3,163	22.5	0.0%	0.1%	0.1%	3.2%
Unknown	34	0.0	0.1%	0.2%	0.5%	3.7%
Percentage of Pediatric Patients						
Less than 2%	7,766	35.3	0.0%	0.0%	0.0%	3.1%
Between 2% and 19%	48	0.2	0.1%	-0.2%	-0.2%	2.7%
Between 20% and 49%	12	0.0	0.0%	-0.3%	-0.4%	2.3%
More than 50%	56	0.0	0.1%	0.0%	-0.2%	2.8%

[1] CY 2022 TPNIES for the Tablo® System and TDAPA for KORSUVA™ will continue in CY 2023 under the ESRD PPS. We estimate approximately $4.8 million in TPNIES and TDAPA spending, of which, approximately $958,000 would be attributed to beneficiary coinsurance amounts.

[2] This column includes the impact of the updates in columns (C) through (E) in Table 31, and of the ESRD market basket increase factor for CY 2023 (3.1 percent), reduced by 0.1 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.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the changes to the outlier payment policy described in section II.B.1.c of this final rule is shown in column C. For CY 2023, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.0 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 outlier policy changes.

Column D shows the effect of the update to the LRS for CY 2023 of 55.2 percent. This update is implemented in a budget neutral manner, so the total impact of this 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 updates to the wage index, as described in section II.B.1.b of this final 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 increase of the wage index floor to 0.6000 and the 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 will be 7.1 percent for facilities located in Puerto Rico and the Virgin Islands, and the largest estimated decrease will be 0.6 percent for facilities in New England.

Column F reflects the overall impact, that is, the effects of the outlier policy changes, the updated wage index, and the payment rate update as described in section II.B.1.d of this final

rule. The ESRD PPS payment rate update is 3.0 percent, which reflects the ESRDB market basket percentage increase factor for CY 2023 of 3.1 percent and the productivity adjustment of 0.1 percent. We expect that overall ESRD facilities will 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 2.0 percent increase to an 8.2 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 will be approximately $ 7.9 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 3.5 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 will 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 finalized our proposal 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) Outlier Methodology Alternatives

As discussed in section II.B.1.c.(4) of this final rule, we are finalizing 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. Continuation of Approved Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2023

(1) Tablo® System

One product, the Tablo® System, that was approved for the TPNIES in CY 2022 will continue to be eligible for the TPNIES in CY 2023. In this final rule we are continuing our CY 2022 estimates into CY 2023. We estimate $2.5 million in spending of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.

(2) KORSUVA™ (difelikefalin)

One renal dialysis drug for which the TDAPA was paid in CY 2022 will continue to be eligible for the TDAPA in CY 2023. CMS Transmittal 11295,[395] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for KORSUVA™ (difelikefalin). The TDAPA payment period began on April 1, 2022 and will continue in CY 2023. As set forth in § 413.234(c), TDAPA payment is based on 100 percent of average sales price (ASP). If ASP is not available, then the TDAPA is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based the CY 2023 impacts on the most current 72x claims data; from April 1, 2022 through July 31, 2022. The average number of beneficiaries per month, receiving KORSUVA™ during this timeframe is 50. However, we anticipate that this number will double in CY 2023 as more ESRD facilities incorporate KORSUVA™ into their business operations. If the estimated 100 beneficiaries were to receive thirteen doses per month (100 * 13 = 1,300) for 12 months, the estimated number of doses would be 15,600 (1,300 * 12 = 15,600) in CY 2023. Although dosing varies by patient weight, we have based our estimates on a single dose vial. Current KORSUVA™ pricing is estimated at $150.00 per single dose vial.[396] Multiplying the 15,600 estimated doses by the current pricing of $150 per single dose vial would result in approximately $2,340,000 in spending (15,600 * $150.00 = 2,340,000), of which, approximately $468,000 ($2,340,000 * 0.20 = $468,000) would be attributed to beneficiary coinsurance amounts.

c. 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

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[395] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022 and is available at: https://www.cms.gov/files/document/r11295CP.pdf

[396] CMS ESRD PPS Transitional Drug Add-on Payment Adjustment Webpage. Payment Amounts for New Renal Dialysis Drugs and Biological Products Currently Eligible for the TDAPA. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Downloads/Drugs-and-Biologicals-Eligible-for-TDAPA.pdf. Accessed on September 12, 2022.

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 final rule, we used CY 2021 data from the Part A and Part B Common Working Files as of July 30, 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 final rule. Table 32 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.

TABLE 32: Impacts of the 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)	Change to LRS (C)	Wage Index Changes (D)	Total Percent Change[1] (E)
All Facilities	5,347	307.4	0.0%	0.0%	2.9%
Type					
Freestanding	5,222	301.9	0.0%	0.0%	2.9%
Hospital based	125	5.6	-0.3%	0.1%	2.8%
Ownership Type					
Large dialysis organization	4,440	257.7	0.0%	0.0%	2.9%
Regional chain	583	32.1	0.1%	0.0%	3.0%
Independent	193	12.0	0.2%	-0.2%	3.0%
Hospital based[2]	125	5.6	-0.3%	0.1%	2.8%
Unknown	6	0.1	0.4%	0.1%	3.5%
Geographic Location					
Rural	910	50.1	-0.6%	-0.1%	2.3%
Urban	4,437	257.4	0.1%	0.0%	3.1%
Census Region					
East North Central	887	54.1	-0.2%	-0.4%	2.4%
East South Central	415	22.9	-0.7%	-0.3%	2.0%

Middle Atlantic	562	33.0	0.2%	0.0%	3.3%
Mountain	306	18.8	0.0%	0.0%	3.1%
New England	139	7.4	0.2%	-0.5%	2.7%
Pacific[3]	678	47.4	0.8%	0.6%	4.5%
Puerto Rico and Virgin Islands	1	0.0	-1.9%	7.6%	8.6%
South Atlantic	1,296	73.5	-0.3%	-0.3%	2.4%
West North Central	343	15.4	-0.3%	-0.2%	2.5%
West South Central	720	34.9	-0.4%	0.2%	2.8%
Facility Size					
Less than 4,000 treatments	598	23.4	-0.2%	-0.1%	2.8%
4,000 to 9,999 treatments	2,336	121.1	-0.2%	-0.2%	2.6%
10,000 or more treatments	2,407	162.6	0.1%	0.1%	3.2%
Unknown	6	0.3	0.0%	-0.4%	2.5%
Percentage of Pediatric Patients					
Less than 2%	5,332	307.1	0.0%	0.0%	2.9%
Between 2% and 19%	14	0.3	-0.3%	-0.1%	2.6%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	1	0.0	0.1%	0.4%	3.5%

[1] This column includes the impact of the updates in columns (C) and (D) in Table 32, and of the ESRD market basket increase factor for CY 2023 (3.1 percent), reduced by 0.1 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.

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 update to the LRS for CY 2023 of 55.2 percent. Column D shows the effect of the CY 2023 wage indices, including the increase to the wage index floor and the 5-percent cap on wage index decreases.

Column E shows the overall impact, that is, the effects of the LRS, wage index updates, and the payment rate update of 3.0 percent, which reflects the ESRDB market basket percentage increase factor for CY 2023 of 3.1 percent and the productivity adjustment of 0.1 percent. We expect that overall ESRD facilities will experience a 2.9 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 2.0 percent to 8.6 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 proposed 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 change will have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $80 million will 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.

d. 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 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 10.1 percent or 795 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. Among an estimated 795 facilities that would receive a payment reduction, approximately 62 percent or 492 facilities would receive the smallest payment reduction of 0.5 percent. 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). Based on our final policies, the total estimated payment reductions for all the 795 facilities expected to receive a payment

reduction in PY 2023 would be approximately $5,548,652.69. Facilities that do not receive a TPS do not receive a payment reduction.

Table 33 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 33: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	6727	89.43%
0.5%	492	6.54%
1.0%	127	1.69%
1.5%	82	1.09%
2.0%	94	1.25%

*325 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 suppressing for PY 2023 as discussed in section IV.B.2 of this final rule. Payment reduction estimates are calculated using the most recent data available (specified in Table 34) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 34.

TABLE 34: 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 Rate*	N/A	N/A
% Catheter*	N/A	N/A
Hypercalcemia	Jan 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021

*Note: We are finalizing our proposals 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 well as to suppress the Standardized Fistula Rate measure for PY 2023, as discussed in section IV.B.2 of this final rule.

For all measures except the seven measures we are suppressing in IV.B.2 of this final 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 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 final policies outlined in sections IV.B and IV.C of this final rule. Facility reporting measure scores were estimated using available data from CY 2021 for MedRec, UFR, Clinical Depression, Hypercalcemia, and NHSN Dialysis Event. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 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 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 47.87 percent or 3,592 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2025. Among an estimated 3,592 facilities that would receive a payment reduction, approximately 55 percent or 1,983 facilities would receive the smallest payment reduction of 0.5 percent. 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). Based on our final policies, the total estimated payment reductions for all the 3,592 facilities expected to receive a

payment reduction in PY 2025 would be approximately $32,457,692.52. Facilities that do not receive a TPS do not receive a payment reduction.

Table 35 shows the overall estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP.

TABLE 35: Estimated Distribution of PY 2025 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	3,912	52.13%
0.5%	1,983	26.43%
1.0%	1,190	15.86%
1.5%	369	4.92%
2.0%	50	0.67%

*343 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 36) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 36.

TABLE 36: 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 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021

*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, to be included in the facility's TPS. For the STrR reporting measure, which we are converting to a clinical measure beginning in PY 2025 in section IV.E.1.b of this final rule, facilities were required to have at least 10 patient-years at risk 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 final policies outlined in section IV.E of this final rule. Facility reporting measure scores were estimated using available data from CY 2021 for MedRec, UFR, Clinical Depression, Hypercalcemia, and NHSN Dialysis Event. 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 final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 37 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.

TABLE 37: 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	7,847	35.0	7,504	3,592	-0.37%
Facility Type:					
Freestanding	7,471	33.7	7,168	3,405	-0.37%
Hospital-based	376	1.4	336	187	-0.49%
Ownership Type:					
Large Dialysis	5,964	27.1	5,843	2,631	-0.33%
Regional Chain	904	4.3	881	471	-0.45%
Independent	466	2.1	437	301	-0.68%
Hospital-based (non-chain)	376	1.4	336	187	-0.49%
Unknown	137	0.1	7	2	-0.21%
Facility Size:					
Large Entities	6,868	31.4	6,724	3,102	-0.35%
Small Entities[1]	842	3.5	773	488	-0.60%
Unknown	137	0.1	7	2	-0.21%
Rural Status:					
1) Yes	1,281	5.0	1,232	502	-0.30%
2) No	6,566	30.0	6,272	3,090	-0.39%
Census Region:					
Northeast	1,087	5.5	1,041	518	-0.39%
Midwest	1,736	6.6	1,657	819	-0.39%
South	3,570	15.2	3,404	1,743	-0.41%
West	1,393	7.4	1,342	466	-0.24%
US Territories[2]	61	0.3	60	46	-0.64%
Census Division:					
Unknown	9	0.1	9	4	-0.33%
East North Central	1,222	4.7	1,180	621	-0.43%
East South Central	618	2.4	594	294	-0.38%
Middle Atlantic	886	4.3	842	443	-0.41%
Mountain	436	1.9	420	137	-0.23%
New England	201	1.2	199	75	-0.29%
Pacific	957	5.5	922	329	-0.24%
South Atlantic	1,827	8.0	1,741	914	-0.43%
West North Central	514	1.9	477	198	-0.29%
West South Central	1,125	4.8	1,069	535	-0.39%
US Territories[2]	52	0.1	51	42	-0.69%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,229	1.9	1,084	318	-0.24%
4,000-9,999 treatments	3,095	10.1	3,058	1,320	-0.33%
Over 10,000 treatments	3,358	22.9	3,354	1,949	-0.45%
Unknown	165	0.2	8	5	-0.50%

[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.

(3) Effects of the PY 2026 ESRD QIP on ESRD Facilities

For the PY 2026 ESRD QIP, we estimate that, of the 7,847 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 47.87 percent or 3,592 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. Among an estimated 3,592 facilities that would receive a payment reduction, approximately 55 percent or 1,983 facilities would receive the smallest payment reduction of 0.5 percent. The total payment reductions for all the 3,592 facilities expected to receive a payment reduction is

approximately $32,457,692.52. Facilities that do not receive a TPS do not receive a payment reduction.

Table 38 shows the overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 38: Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	3,912	52.13%
0.5%	1,983	26.43%
1.0%	1,190	15.86%
1.5%	369	4.92%
2.0%	50	0.67%

*Note: 343 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 39) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 39.

TABLE 39: 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 2019-Dec 2019	Jan 2021-Dec 2021
NHSN BSI	Jan 2019-Dec 2019	Jan 2021-Dec 2021

*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, to be included in the facility's TPS. For the STrR reporting measure, which we are converting to a clinical measure beginning in PY 2025 in section IV.E.1.b of this final rule, facilities were required to have at least 10 patient-years at risk 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 final rule. Facility reporting measure scores were estimated using available data from CY 2021 for MedRec, UFR, Clinical Depression, Hypercalcemia, and NHSN Dialysis Event. 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 final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2021 and December 2021 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 40 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.

TABLE 40: 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	7,847	35.0	7,504	3,592	-0.37%
Facility Type:					
Freestanding	7,471	33.7	7,168	3,405	-0.37%
Hospital-based	376	1.4	336	187	-0.49%
Ownership Type:					
Large Dialysis	5,964	27.1	5,843	2,631	-0.33%
Regional Chain	904	4.3	881	471	-0.45%
Independent	466	2.1	437	301	-0.68%
Hospital-based (non-chain)	376	1.4	336	187	-0.49%
Unknown	137	0.1	7	2	-0.21%
Facility Size:					
Large Entities	6,868	31.4	6,724	3,102	-0.35%
Small Entities[1]	842	3.5	773	488	-0.60%
Unknown	137	0.1	7	2	-0.21%
Rural Status:					
1) Yes	1,281	5.0	1,232	502	-0.30%
2) No	6,566	30.0	6,272	3,090	-0.39%
Census Region:					
Northeast	1,087	5.5	1,041	518	-0.39%
Midwest	1,736	6.6	1,657	819	-0.39%
South	3,570	15.2	3,404	1,743	-0.41%
West	1,393	7.4	1,342	466	-0.24%
US Territories[2]	61	0.3	60	46	-0.64%
Census Division:					
Unknown	9	0.1	9	4	-0.33%
East North Central	1,222	4.7	1,180	621	-0.43%
East South Central	618	2.4	594	294	-0.38%
Middle Atlantic	886	4.3	842	443	-0.41%
Mountain	436	1.9	420	137	-0.23%
New England	201	1.2	199	75	-0.29%
Pacific	957	5.5	922	329	-0.24%
South Atlantic	1,827	8.0	1,741	914	-0.43%
West North Central	514	1.9	477	198	-0.29%
West South Central	1,125	4.8	1,069	535	-0.39%
US Territories[2]	52	0.1	51	42	-0.69%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,229	1.9	1,084	318	-0.24%
4,000-9,999 treatments	3,095	10.1	3,058	1,320	-0.33%
Over 10,000 treatments	3,358	22.9	3,354	1,949	-0.45%
Unknown	165	0.2	8	5	-0.50%

[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.

(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 $32,457,692.52 in Medicare savings. For comparison, Table 41 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2026.

TABLE 41: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2026

Payment Year	Estimated Payment Reductions
PY 2026	$32,457,692.52
PY 2025	$32,457,692.52
PY 2024	$17,104,030.59 (86 FR 62011)
PY 2023	$5,548,652.69
PY 2022	$0[397] (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

[397] 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.

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 final rule, we are finalizing the suppression of seven measures for PY 2023 due to the impacts of the COVID-19 PHE on CY 2021 data. We considered not suppressing these seven 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.

e. 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 in this final rule (discussed in detail in section V.B of this final rule) will impact model payment adjustments for PPA Period 5, starting July 1, 2024. The change that is most likely to affect the impact estimate for the ETC Model is the additional 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 final rule. We do not anticipate that the policy to clarify the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers or the policy to post certain model data, described in section V.B.2 of this final rule, will 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 changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the 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 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 change described in section V.B.1 of this final 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 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 Achievement Scoring Update

TABLE 42: 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.

Table 42 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 42, 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 in this final rule will 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 in this final rule will 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 in this final rule will 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 final 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 final rule addresses a model specific to ESRD. It provides descriptions of the

requirements that we will waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives considered. 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 43 showing the classification of the impact associated with the provisions of this final rule.

TABLE 43: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2023)	
Category	**Transfers**
Annualized Monetized Transfers	$230 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	-$5.5 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2025	
Category	Transfers
Annualized Monetized Transfers	-$32 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-$32 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

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[398], 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 will have total revenues of more than $9.5 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 474 facilities that are independent and 376 facilities that are hospital-based, as shown in the ownership category in Table 31 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 825 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in

398 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).

our data set. In total, accounting for the 382 nonprofit ESRD facilities that are also considered small businesses, there are 1,293 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 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 3.1 percent increase in payments for CY 2023. An independent facility (as defined by ownership type) is likewise estimated to receive a 3.2 percent increase in payments for CY 2023. As shown in Table 31, we estimate that the overall revenue impact of this final 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 will 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 3,592 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2025 ESRD QIP, 488 are ESRD small entity facilities. We present these findings in Table 35 ("Estimated Distribution of PY 2025 ESRD QIP Payment Reductions") and Table 37 ("Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025").

For the ETC Model, this final 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 beneficiaries; we have determined that the provisions of the final rule for the ETC Model will 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 beneficiaries; we have determined that the provisions of the final rule will 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 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 final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 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 2.2 percent increase in payments. Therefore, the Secretary has certified that this final 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 final 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 final 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.

I. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

VIII. 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-F 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 October 25, 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 amends 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, Standardized Fistula 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 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) (effective January 1, 2025) 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.

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(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.

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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: October 27, 2022

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Xavier Becerra,

Secretary,

Department of Health and Human Services.

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